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Development and Validation of a Hybrid Virtual/Physical Nuss Procedure Surgical Trainer

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DEVELOPMENT AND VALIDATION OF A HYBRID VIRTUAL/PHYSICAL NUSS PROCEDURE SURGICAL TRAINER

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ABSTRACT

DEVELOPMENT AND VALIDATION OF A HYBRID VIRTUAL/PHYSICAL NUSS PROCEDURE SURGICAL TRAINER

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With continuous advancements and adoption of minimally invasive surgery, proficiency with nontrivial surgical skills involved is becoming a greater concern. Consequently, the use of surgical simulation has been increasingly embraced by many for training and skill transfer purposes. Some systems utilize haptic feedback within a high-fidelity anatomically-correct virtual environment whereas others use manikins, synthetic components, or box trainers to mimic primary components of a corresponding procedure.

Surgical simulation development for some minimally invasive procedures is still, however, suboptimal or otherwise embryonic. This is true for the Nuss procedure, which is a minimally invasive surgery for correcting pectus excavatum (PE) – a congenital chest wall deformity. This work aims to address this gap by exploring the challenges of developing both a purely virtual and a purely physical simulation platform of the Nuss procedure and their implications in a training context. This work then describes the development of a hybrid mixed-reality system that integrates virtual and physical constituents as well as an augmentation of the haptic interface, to carry out a reproduction of the primary steps of the Nuss procedure and satisfy clinically relevant prerequisites for its training platform.

Furthermore, this work carries out a user study to investigate the system's face, content, and construct validity to establish its faithfulness as a training platform.

My humble work I dedicate to the person whose presence in my life for the past twenty nine years taught me diligence, confidence, perseverance, and full belief in myself: My Father (Brigadier General) Dr. Fayez Radi Obeid Ayasra. For supporting me to pursue my dreams and ambitions, for your firm counsel yet gentle heart, for giving us everything even though you grew up with nothing, and for instilling in me the values of life and the fear of God Almighty.

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To Suzan Abandah: my dear, warm, and amazing Mother. Your care, tireless prayer, and love are what kept me going all these years. The proud and profound smile I saw on your and on my Father's faces at the completion of my doctoral work is the ultimate outcome that has continuously fueled my momentum.

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CHAPTER I

INTRODUCTION

Over the past two decades, minimally invasive procedures (MIP) have rivaled the popularity of conventional approaches in scarring, recovery times, and pain medication aspects. It is often argued, however, that such procedures pose a prolonged learning curve for most novice surgeons. Preoperative training and proper surgical planning can alleviate such limitations. In the early stages, such planning existed in the form of collaboration between radiologists and surgeons using three-dimensional representations of organs and body components constructed from MRI and/or CT images for preoperative planning such as for colonoscopy [1] and craniofacial surgery [2]. In principle, high fidelity surgical simulators can be employed for surgical training and education and proved to be an advantageous part of teaching curricula [3][1].

Today, several commercially available and under development simulators exist for most common endoscopic, laparoscopic, and, in general, minimally invasive procedures. SimSurgery's Educational Platform for laparoscopic procedures [4], Simbionix's numerous mentors for laparoscopic, endoscopic, arthroscopic, endovascular and other procedures [5], SurgicalScience's procedural simulation systems for cholecystectomy, appendectomy, suturing and anastomosis [6], and Mentice's Minimally Invasive Surgical Trainer (MIST) [7], are all examples of such simulation systems. Others are developing simulation and training systems to aid in medical robotics. Among those are projects that seek skill transfer and training for operating the da Vinci surgical robot. Although Mimic's dV-Trainer [8] is

[1] IEEE Transactions on Biomedical Engineering style is used in this dissertation for formatting figures, tables, and references.

a pioneer in this area, Simulate Surgical Systems' RoSS [9] and Simbionix's Robotix Mentor [10] are not far behind.

According to Milgram and Kishino [11], the conventional view of a virtual reality (VR) environment is one where the user views, and interacts with, a completely synthetic world that consists of virtual objects. On the other extreme of their virtuality continuum, a real environment is one that consists solely of real objects. A display system that falls somewhere between the two and involves a merge of real and virtual worlds is referred to as *mixed reality* (MR). A similar classification was provided by [12, 13] in a clinical context, where they described that within a continuum between physical manikins and virtual environment simulators, are hybrid simulators that combine anatomical models with VR and haptic interfaces. This concept of *mixed reality* is carried out in this work and will be used with the term *hybrid simulation* interchangeably. This definition of a hybrid excludes simulators that use physical ports or trocars mounted on arbitrary objects like a box or hemisphere and focuses on those that use an anatomically-correct manikin.

1.1 Motivation

Pectus Excavatum (PE) is a congenital chest wall deformity characterized by a deep depression of the sternum, affects 1 to 8 per 1,000 live births [14], and is often accompanied by other problems such as scoliosis, fatigue, and breathing issues [15]. In the Nuss procedure (a minimally invasive procedure to correct PE), a small incision is made on each side of the chest to insert a pre-bent steel bar from the side of the chest and secured it beneath the funneled area to elevate and support the sternum pushing out the sunken part of the ribcage. The surgeon uses a thoracoscope to monitor the procedure internally in addition to the external view of the patient's torso [16-18].

Surgical trainers and simulators have been developed for various minimally invasive procedures cultivating a rapidly growing area of research. However, a surgical simulator and trainer for the Nuss procedure has not been introduced to date. Rechowicz *et al.* [19, 20] described the development and validation of a Nuss procedure planner including a force–deflection model to predict the sternum position as well as an average shape of the chest to assess performance measures of surgical outcomes. Furthermore, their work emphasized the necessity and benefits of a surgical trainer to complement the function of the planner.

1.2 Problem Statement

Simulating a non-laparoscopic minimally invasive procedure (which involves instruments other than common laparoscopic graspers, scissors, dissectors, etc.) or a procedure that doesn't involve using a trocar for tool insertion can be challenging. Depending on the procedure, a physical constituent can be of great significance to enhance realism. Many of the aforementioned surgical simulators use physical components when simulating external behaviors such as a tool insertion process, whereas others utilize haptic feedback. A simulator that integrates a physical component representing an anatomically correct part of the body (a manikin) with a virtual environment displayed on a monitor is referred to, in this work, as a *hybrid simulator*.

Similar challenges were faced by Kotranza *et al.* (2008) who indicated the need for a virtual/physical integration for training on clinical breast cancer examination by augmenting a physical manikin with a collocated virtual human avatar. They indicate that using only manikins lacks the ability to provide user performance feedback, is hardly patient-specific, and isn’t a practical platform to introduce surgical complications or scenarios [21].

A research group at the University of Virginia developed a VR simulator for the tube thoracostomy procedure [22, 23]. Two years later, after facing the limitations of a fully virtual setup, they opted to improve it by incorporating the virtual environment with a chest manikin [24]. Their system design demonstrates the limitations of a fully virtual simulation for tasks that involve an insertion mechanism and highlights the advantages that physical components add.

Li *et al.* found a similar motivation to adopt a mixed reality simulation for arthroscopic knee surgery. In their system, they couple an artificial knee joint and actual surgical tools with a synchronized 3D computer generated model of the joint. Their study showed the system’s potential to enhance navigational skills for novice residents [25].

Due to the unusual complexities of the Nuss procedure, the need for a hybrid trainer that addresses the most significant aspects for positive training is unambiguous. “*An interactive haptic-incorporated real-time hybrid training simulator for non-trocar-based minimally invasive surgeries such as the Nuss procedure can be developed utilizing and combining the better elements of a virtual and a physical implementation.*” It is believed that this hybrid simulator will outperform a fully virtual or fully physical version of the trainer and, furthermore, provide a more efficient reproduction for procedures that involve a movable pivot behavior of surgical tools.

1.3 Proposed System

As stated earlier, a simulator and trainer for the Nuss procedure would be the first of its kind. The work of Rechowicz [20] touched on this topic by describing the need for such a system but was, however, steered toward the development and validation of a patient-specific planner. It is, therefore, the intent to complement that work with a real-time training platform that simulates a pectus excavatum deformity and can be employed to, preoperatively, enhance surgical skills as well as alleviate risks of complications during surgery. This training platform will emphasize the surgical skills unique and crucial to the Nuss procedure, namely the sternal elevation and the mediastinal dissection (tunneling) skills. The Nuss Procedure Surgical Trainer (NPST), utilizes patient-specific data to create a computer-generated virtual model of the patient and the deformity; and allows the user to interact with the environment through a haptic interface. More specifically, this research addresses the following aims:

- **Aim 1**: Develop a fully virtual Nuss procedure simulator.
- **Aim 2**: Develop a fully physical anatomically correct training manikin (physical simulator) that replicates the PE deformity.
- **Aim 3**: Deconstruct the Nuss procedure into comparable task-based components and compare corresponding virtually- versus physically-reproduced counterparts using clinically relevant criteria.
- **Aim 4**: Investigate the advantages and limitations of both implementations to produce a hybrid scheme that utilizes the better of each and fulfills the training requirements of the surgery.

- **Aim 5**: Demonstrate face, content, and construct validity of the surgical trainer.

This work is closely supervised by pediatric surgeons at the Children's Hospital of The King's Daughters who pioneer in developing, enhancing, and training of the Nuss procedure.

1.4 Contributions

This dissertation aims to contribute in three original aspects. First is an integrated Nuss procedure surgical trainer; second, a framework for comparing virtual versus physical simulation platforms for surgery; and third, a methodology for reproducing pivot mechanics for surgical tool insertion using a haptic interface.

1.4.1 A Nuss procedure surgical trainer (NPST)

The first contribution of this dissertation is the development of a training platform for the Nuss procedure. To date, a simulation-based trainer specifically designed for components of this surgery does not exist. The main challenge is the uniqueness of the surgical techniques and instruments involved in the Nuss procedure. Unlike in most minimally invasive procedures where laparoscopic/endoscopic surgical instruments are used (such as forceps, graspers, and dissectors), the Nuss procedure is performed using a surgical instrument specifically designed for this surgery only. The shape and function of this instrument (introducer) requires specialized modeling techniques to be properly simulated (see 1.4.3). Additionally, the surgical technique itself involves an intricate set of steps to identify, maneuver, and dissect a particular anatomical region, otherwise not approached by other surgical procedures.

Consequently, the steps and components of the Nuss procedure prevent it from being grouped or classified with other minimally invasive surgeries which, therefore, necessitates the availability of its own training platform. In this work, a synchronized hybrid platform that integrates a semi-manikin of the thorax with a haptic-incorporated virtual environment is developed with facilities that attend specifically to the characteristics of the Nuss procedure as described by Obeid *et al*. in [26]. This work also establishes the validity of the developed platform as a training instrument.

This contribution produced a system that allows the user to interact with the simulated surgery in two interfaces: a haptic interface and an active manikin. In addition to using the haptic interface to control the surgical tool, the user can perform physical alterations to the manikin, i.e., affecting the physical model of the sternum on the training thorax. These alterations are translated synchronously and mapped to corresponding behaviors in the virtual environment using appropriately placed sensors.

This development also necessitated the introduction of a multi-model architecture for simulating organs in the virtual environment. In this architecture, four distinct models were incorporated for each organ including a render model, a deformation model, a haptic model, and an information model. These models differ in attributes, functionality, and responses to collisions. Collectively, the four models accomplish realistic visualization, soft-body deformation, haptic interactivity, as well as user performance recording, respectively. This configuration parallelizes the different functionalities to ensure an adequate representation of behaviors; by simulating collision-based deformations as well as force feedback without sacrificing fidelity.

1.4.2 A simulation framework: Virtuality and Interactivity

The second contribution of this dissertation is the development, formulation, and implementation of a framework for analyzing a surgical procedure (pediatric, thoracic, or otherwise), convert its steps into a task breakdown, and then map the tasks to appropriate simulation components to reproduce the procedure's mechanical and ergonomical behaviors. This is performed navigating within a 2-dimensional continuum for hybrid simulators composed of a virtual-physical reality dimension (degree of virtuality), as well as an active-passive dimension (degree of interactivity). The degree of virtuality vs. physicality of the components that make up the trainer places it closer to the left or to the right extreme of the *x*-axis of the continuum, respectively. Similarly, the degree of interactivity between the user and the system (in the form of visual or haptic feedback) as well as the multiplicity of input modalities at the user's disposal (controlling a haptic device, changing the posture of a physical component, and/or using multiple surgical tools) affects a trainer's placement along the *y*-axis of the continuum.

This framework contributes to research areas and disciplines related to computer aided intervention, evaluation, and assessment as well as medical modeling and simulation. This framework also explores the employability of haptic-incorporated virtual environments, anatomy and pathology modeling, synthetic materials and physical phantoms, as well as 3D printing and rapid prototyping techniques for such simulation systems. Additionally, it can have numerous extensions specifically as it relates to the scalability of training systems (stationary/high-fidelity platforms vs. portable low-detailed ones) as well as to efforts to address implications of surgical simulation with respect to fidelity and latency.

1.4.3 Surgical instrument pivot reproduction

The third contribution is the investigation of various approaches to reproduce a surgical tool's pivot behavior in minimally invasive surgery as well as the development of an augmentation for generic haptic devices to better achieve this functionality.

This work explores multiple virtual and physical techniques to model and simulate a surgical tool's behavior once inserted into the body [27-29] by exploiting and demonstrating the limitations of solely utilizing the capabilities of generic haptic devices and identifies the inherent discrepancies produced accordingly. This work then introduces a prototyped supplemental component for generic haptic devices to augment their real-time motion tracking and eliminate the error in force vectors produced by the discrepancy between natural and virtual pivots. This is achieved by synchronizing the coordinate systems of the physical and virtual environments, aligning virtual and natural (physical) pivot points, and compensating for the described discrepancy with a mechanism that implements and simulates tool insertion as shown by Obeid *et al*. in [30].

1.5 Dissertation Organization

The work in this dissertation is organized in 7 chapters. **Chapter Two** introduces the terminology and technical background relating to using surgical simulation for training as well as discusses validation approaches for surgical simulators and trainers.

Furthermore, it details the current apprenticeship of surgical training in general and of the Nuss procedure in particular as well as provides an analysis of existing research in the literature for developing such platforms.

The development methodology and implementation of a fully virtual Nuss procedure simulator are detailed in **Chapter Three** fulfilling *aim one*. *Aim two* is addressed in **Chapter Four** where a fully physical (manikin-based) simulator for the Nuss procedure is constructed.

Chapter Five presents the methods and approaches used to develop the ultimate improved iteration of the surgical trainer: The Hybrid model. The chapter presents a task-breakdown and analysis of the surgical procedure to justify employing virtual or physical implementations of various components of the simulation. The findings and results of the developed hybrid system as well as the outcomes of an in-vitro validation experiment are presented in this chapter as well. This chapter directly corresponds to *aims three* and *four*.

Chapter Six discusses the approaches and outcomes for conducting performance, clinical, and user evaluation experiments to establish face, content, and construct validity of the surgical trainer; addressing, thus, *aim five* of the dissertation.

Finally, **Chapter Seven** provides a conclusion and summary of the dissertation and generalizes its outcomes for other purposes. The manner in which each of the dissertation aims were addressed is briefly reiterated and potential extensions and improvements of this work are described.

CHAPTER II

BACKGROUND AND PREVIOUS WORK

To build a knowledge infrastructure for the succeeding chapters and to clearly articulate the discussed topics, the theoretical background is introduced first in this chapter. This includes medical significance and clinical aspects pertaining to the work developed in this dissertation as well as a synthesis of existing simulation platforms and approaches.

Additionally discussed are the various validation approaches and protocols followed for evaluating surgical simulators and trainers. This involves a thorough literature analysis that highlights the primary criteria to validate a surgical simulator as well as the applicability of these criteria to various surgical training platforms.

Following the theoretical background, a literature synthesis and review of related work is presented. When approaching the underlying issues of developing such a surgical simulator and trainer, several areas of research are investigated:

1) Studies that explored simulating the Nuss procedure and associated tasks are of a prioritized focus.
2) Research involving comparisons between virtual and physical simulation setups of a specific procedure are examined. Particularly beneficial, are those that showed a justification to transition parts of the simulation from a virtual to a physical scheme and vice versa; as well as those that combine virtual with physical constituents for surgery simulation.
3) Since the Nuss procedure involves surgical tools that are not widely used across other minimally invasive procedures (MIPs), insights will be sought from research work involving the development of surgical trainers for procedures of

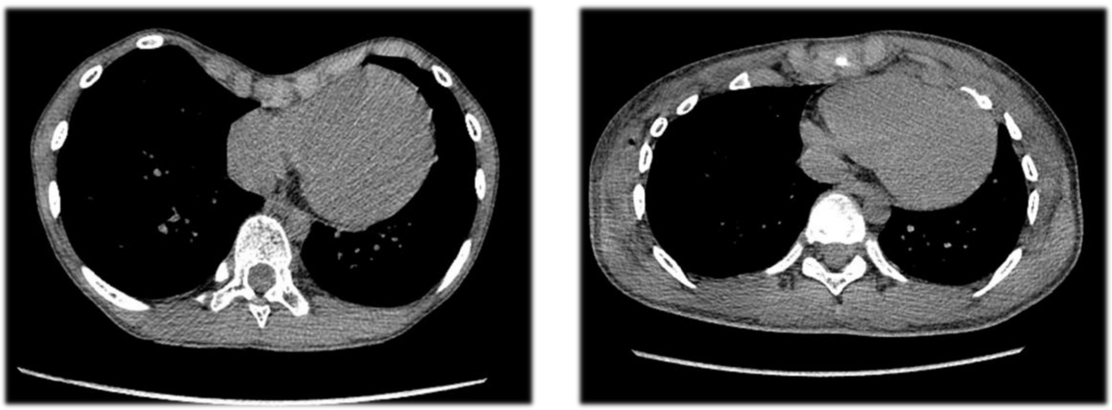
similar characteristics to the Nuss procedure, or those that simulate a non-laparoscopic minimally invasive surgery.

2.1 Pectus Excavatum

Pectus Excavatum (PE) (a Latin term meaning hollowed chest) is a congenital deformity in which several ribs as well as the sternum grow abnormally causing depression of the anterior chest wall (Fig. 1 (a)). In this condition, the sternum articulates posteriorly toward the spine [15]. This deformity is often observed at birth and can develop with growth [31]. PE is the most common chest wall anomaly in children affecting 1 to 8 per 1,000 live births [14], and males more than females by a factor of 4:1 [32]. PE patients often experience limited cardiac and respiratory function as well as social anxiety and psychological stress [15, 33].

Cartoski *et al*. classified PE using the following criteria: (i) localized versus diffused depression, also known as cup versus saucer, (ii) length of the depression, (iii) symmetry, (iv) sternal torsion, (v) slope and position of absolute depth, and (vi) unique patterns of the deformation [34]. Frequency distribution of subtypes of typical PE and rare types was performed by Kelly *et al*. on a random sample of 300 patients with non-syndromic PE [35]. Over two-thirds of analyzed PE morphologies were characterized by the cup and 21% by the saucer type PE. The remaining 11% were characterized by the trench type PE and very rare Currarino-Silverman which is a mix between PE and pectus carinatum (PC). The deepest point of PE in most cases was located to the right of the midline and in the inferior part of the sternum.

Depending on the severity of this condition, surgery may be recommended as the treatment of choice. Several indices were introduced to quantify PE's severity using computed tomography (CT) scans [36]. Haller index (HI), introduced in 1987 and considered the gold standard for assessing Pectus Excavatum (PE) severity, is the current prerequisite for insurance reimbursement [37]. A surgical intervention is generally recommended for a patient with a Haller Index (HI) larger than 3.25.



(a) (b)

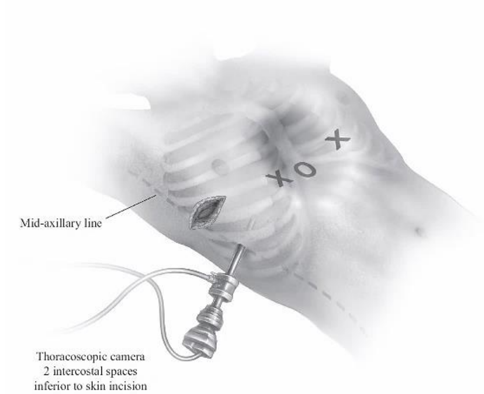
Fig. 1. Computed tomography (CT) scan in axial plane for a patient with PE before (a) and after (b) the Nuss procedure surgery (courtesy of Beijing Children's Hospital).

2.2 Nuss Procedure

Several techniques have been developed for PE correction including the Ravitch technique [38], the Robicsek technique [39], and the Vacuum bell [40]. The minimally invasive repair of Pectus Excavatum (MIRPE), often referred to as the Nuss Procedure, was developed by Dr. Donald Nuss of the Children's Hospital of the King's Daughters, Norfolk, VA, USA. This technique has recently become more and more popular as it requires no cartilage incision or sternal osteotomy. It was performed in 1987 for the first time and a 10-year experience of the technique was reported in the *Journal of Pediatric Surgery* in 1998 [16-18].

The Nuss technique is performed by making two small incisions on either side of the chest. The surgical tool, *Introducer* (Fig. 2), is then inserted from the right side and guided along posterior to the sternum and ribs and anterior to the pericardium (mediastinal dissection or tunneling) to make a pathway to the other side of the chest (Fig. 3 (b-d)). A third incision is made to insert a thoracoscope to provide an internal view and guide the procedure (Fig. 3 (a)). A pre-concaved stainless-steel bar is then inserted under the sternum through the pathway (Fig. 3 (e)). The bar is then flipped elevating and correcting the sternum and the bar is fixed in place and supported by a stabilizer and PDS sutures (Fig. 3 (f)). After two to four years, the bar is removed from the patient's chest (Fig. 1 (b)).

Fig. 2. Surgical tool used in the Nuss procedure: the introducer [41].



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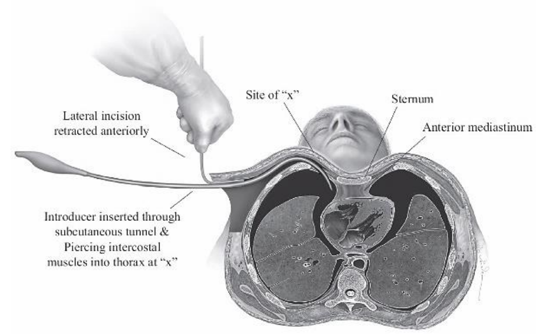

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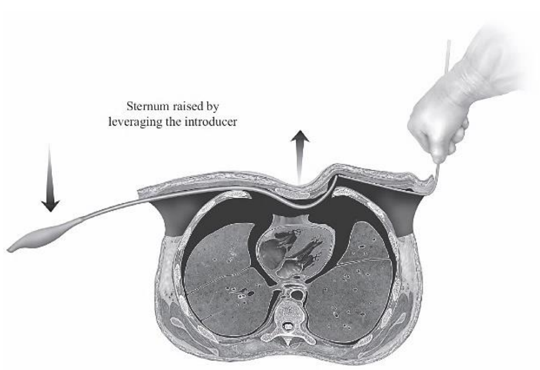

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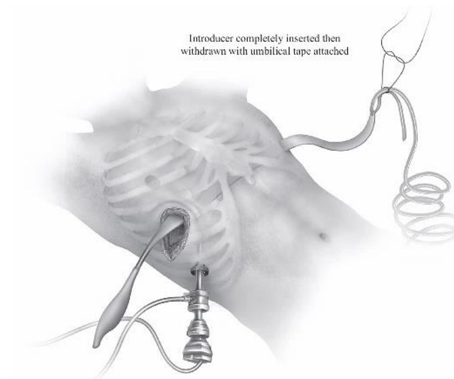

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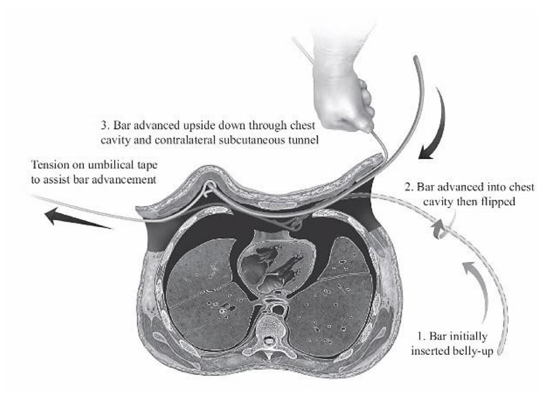

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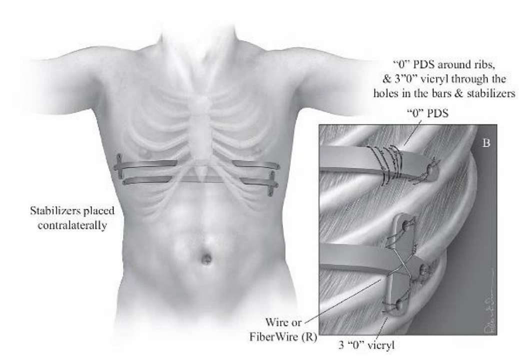


(f)

Fig. 3. Main steps of the Nuss procedure: (a) incision and thoracoscope sites, (b) inserting introducer into thorax, (c) mediastinal dissection and pivot around insertion point, (d) reaching exit site and using umbilical tape, (e) pulling pectus bar under sternum, and (f) stabilizing the bar(s). (Reprinted from [42] with permission. © Elsevier Inc., 2014).

Nuss and Kelly [42] indicated several nuances of the procedure that would significantly influence its success. They emphasize the importance of constantly keeping the tip of the introducer in sight during mediastinal tunneling. They point out that performing an initial sternal elevation before attempting to create the pathway is necessary, particularly for severe and complex cases where the tip of the introducer is completely occluded by the deformity after a mere distance of two centimeters or less. This directly minimizes the risk of cardiac or pulmonary injury. Sternal elevation can be accomplished either by: (a) using an extra introducer placed 1-2 intercostal spaces superior to the deformity's deepest point, (b) using Klobe's Vacuum bell [40], (c) using Park's Crane technique [43] utilizing a Rultract Retractor system [44] (Fig. 4), or (d) manually elevating the sternum using a Volkmann bone hook through in insertion lateral to the sternum [45].

Fig. 4. Sternal elevation with Park's Crane technique [43]. Using a bed-mounted Rultract Retractor system to elevate the sternum and improve thoracoscopic view. (Reprinted from [42] with permission. © Elsevier Inc., 2014).

Cardiac injury has been commonly considered the most dreaded complication of the Nuss procedure after being reported for the first time in 1998 [46]. The first reported patient death from intraoperative cardiac perforation was brought to light in 2008 [47]. Furthermore, Castellani *et al*. described intraoperative cardiac perforation as the most serious Nuss procedure complication and listed it as one of seven major ones that occurred in 4.2% of 167 Nuss operations they included in their study [48]. Most of such studies that reported cases of intraoperative cardiac perforation indicated that patients sustained the injury during the surgeon's mediastinal dissection or tunneling.

As thoroughly explained by Nuss and Kelly [42], to perform a safe and correct mediastinal dissection (Fig. 5 (a)), the surgeon uses the posterior surface of the introducer to perform an anterior to posterior or "pawing" motion to peel off the pleura covering the anterior part of the pericardium under the surface of the sternum (Fig. 5 (b)). A foamy tissue is then visualized creating the first part of the tunnel. The dissection is then slowly continued until the introducer reaches the left side of the thorax. This behavior is unique to the Nuss procedure yet must be performed meticulously to avoid unfortunate consequences which may include bleeding, hematoma, or cardiac perforation. With this rationale, a training platform that focuses on this aspect of the procedure can be of significant benefit.

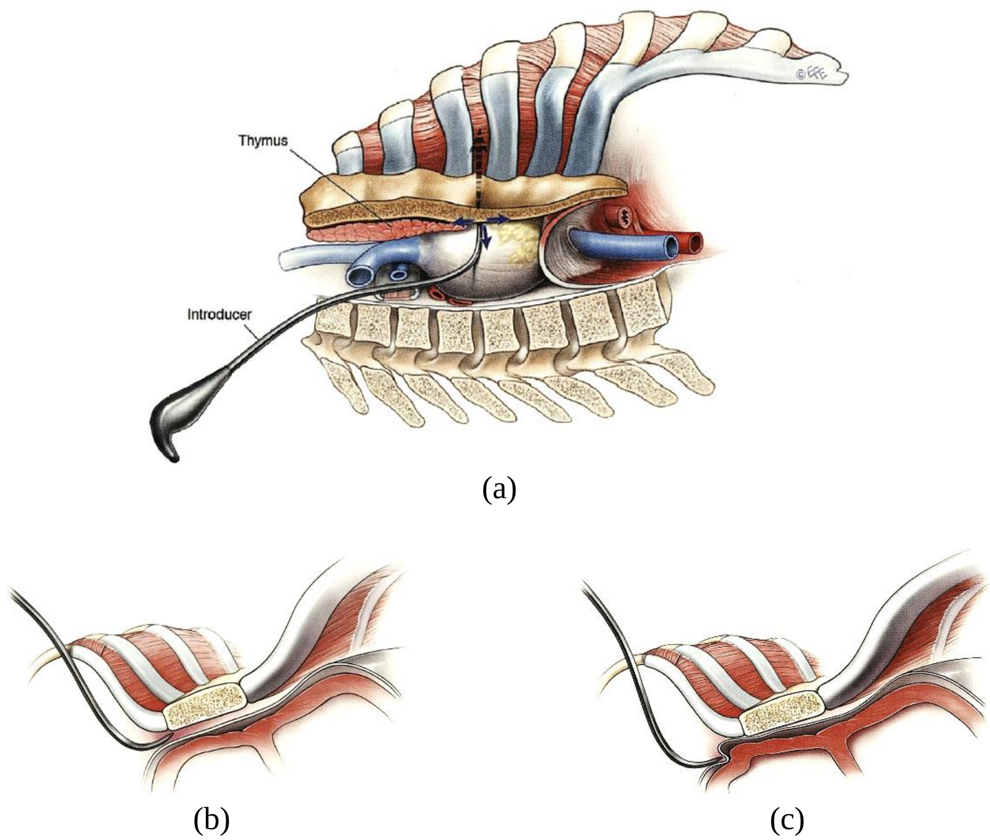


Fig. 5. Mediastinal dissection using the introducer (a), an illustration of (b) a correct approach using the tool's undersurface, and of (c) an incorrect approach using the tip for dissection (potential complication). (Reprinted from [49] with permission. © Springer-Verlag Berlin Heidelberg, 2015).

2.3 Approaches for Surgical Simulation

Surgical simulation is an instructional strategy utilized to transfer required surgical skills by involving the learners in scenarios that emulate realistic situations. It is generally used to train medical students on specific procedures to achieve eye-hand coordination and the ability to learn the primary steps of the procedure hands-on. In addition, surgical simulation allows for a repetitive performance of a specific task to enhance the trainee's skills, speed, and efficiency.

Similar to the way to Milgram and Kishino *et al.* classified generic visual displays along a virtuality continuum [11], an equivalent model was described by Lindeman as it related to visual, haptic, and other cues [50]. The Australian Safety and Efficacy Register of New Interventional Procedures (ASERNIP) – Surgical followed a similar classification of surgical simulation types, but referred to simulators that combine physical components with virtual environments as hybrid simulators in one systematic review in 2007 [12], and as augmented reality simulators in another in 2012 [13]. Synthesizing the perspectives of these three groups, the relevant types of surgery simulations are described here.

2.3.1 Live animal models

Live animals are used for surgery training to provide a realistic, non-patient environment where the trainee can develop simple skills required in the operating room. Animals range in anatomical differences and similarities to humans which makes some animals better simulation candidates than others.

2.3.2 Human cadavers

In this type, cadavers are used to provide the trainee with a detailed understanding of human anatomy. In addition to the benefits in anatomical teaching, human cadavers are used to train procedures including laparoscopy, endoscopy, and others [51, 52].

2.3.3 Synthetic models, box trainers, and manikins

Physical (synthetic) models and box trainers use models of plastic, rubber, and latex materials to mimic different organs and pathologies. In box trainers, the actual surgical instruments and optical devices are usually used to reflect a realistic experience. This type is generally used as a low-cost, portable platform for part-task trainers but is limited in aspects such as time required to replace components, level of realism, haptic forces, and lack of capability for performance quantification [53].

Nonetheless, some have found that a manikin's ability to provide both a visual representation as well as a tactile and tangible interface for identifying landmarks and training on specific tasks to be very beneficial. Currently, Delletec provides several synthetic components for simulating various surgical procedures including appendectomy, breast biopsy, laparoscopy, and many others [54]. SimuLab offers synthetic and physical models and manikins for numerous open and laparoscopic surgeries as well as box trainer modules. TraumaMan is considered one of their popular systems [55]. However, these systems generally lack user performance assessment and are not easily adaptable to patient-specific parameters and scenarios.

2.3.4 Virtual Reality (VR) simulators

Virtual reality has been widely used for training on minimally invasive surgery and provides a more customizable and flexible platform to introduce cases to the training program. In virtual reality surgical simulators, computer generated instruments are used to manipulate computer generated objects in a virtual environment through specially designed interfaces. A high-fidelity simulator of this type is usually expensive and poses great computational challenges for soft tissue modeling but provides a platform for collecting objective metrics such as completion time, number of errors, and other measures for speed and efficiency as well as tactile (haptic) feedback.

Peterisk *et al.* (2002) worked on reproducing haptic volume interactions for bone surgery simulations. Recently, VOXEL-MAN commercialized their fully virtual Tempo and Dental simulators for training surgical access to the structures of the middle ear, and for training on dental procedures, respectively [56, 57]. A similar all-virtual surgical simulator was developed by Choi *et al.* (2009) for the phacoemulsification procedures of cataract surgery [58]. Heng *et al.* (2004) built a tailored force feedback device that compensates for all related forces within the surgical simulation for arthroscopic surgery [59]. Many others have developed and commercialized VR simulators for endoscopic procedural tasks such as camera navigation, instrument manipulation, perceptual-motor skills coordination, grasping, cutting, clipping, dissection, and suturing. SimSurgery's Education Platform [4], Surgical Science's LapSim [60], Simbionix's LapMentor [5], and CAE Healthcare's LapVR [61] are such products for laparoscopic surgery. For other endoscopic procedures, Surgical Science's EndoSim [62], Simbionix's Bronch Mentor [63], and CAE Healthcare's EndoVR [64] are available.

2.3.5 Hybrid (Mixed) Simulators

Some systems have proven a more practical, realistic, and efficient reproduction of surgical procedures when composed of an integration of a physical manikin with a virtual environment. Hybrid simulators are a combination of physical and VR simulators, where a physical object (usually a manikin) is linked to a computer program that provides visual images and/or feedback [65]. The virtual component, i.e., the computer program, produces patient responses and simulation dynamics, whereas the physical component provides the ability to interact with the patient's physical constructs.

Simbionix commercializes Arthro Mentor for arthroscopic training which combines fiberglass/polyurethane anatomical models (shoulder, knee and hip) with 3D images and a haptic interface, allowing the user to operate the actual instruments and the arthroscopic camera [66]. CAE Healthcare provides VirtaMed ArthroS for knee and shoulder arthroscopy training in a mixed reality environment that integrates anatomical rubber models of a knee or shoulder with a corresponding virtual environment, also allowing the user to train on the original surgical tools [67].

2.4 Validation of Surgical Simulators and Trainers

For decades, many have committed to surgical simulation development. The appearance of surgical simulators in the training scene is, however, relatively recent compared to other domains such as aviation and military [68]. It is generally accepted that simulators need to be validated before being integrated into surgical education curriculums [69-73].

Definitions of different validity types for medical simulations were adopted from educational and psychological testing standards constructed by the American Educational Research Association (AERA), American Psychological Association (APA), and the National Council on Measurement in Education (NCME) in 1974 [74]. Many studies have been conducted to address an established set of validity types for surgical simulators/trainers such as *face*, *content*, *construct*, *criterion*, *concurrent*, *transfer*, and *predictive* validities [72, 75-79]. Although the types of validity addressed aren't uniformly defined across different studies, a widely accepted recommendation for validation of surgical simulators is that of Gallagher *et al.* [80].

The literature also generally agrees that validation approaches can be classified into subjective (for face and content validities) and objective (for construct, discriminative, concurrent and predictive validities) [72, 75-78, 81]. Subjective validity approaches typically require experts (surgeons) and novices (medical residents, trainees, or students) to complete a questionnaire about their experience after using the simulator. Objective approaches typically involve experiments to evaluate the simulator's ability to discriminate between the various levels of expertise by collecting real-time metrics that describe the user's performance.

In this section, a literature analysis is performed to establish which types of validity are addressed more commonly than others for validating surgical simulation and training platforms. Following that, these relevant types of validity are defined and the approaches to establish each are discussed.

2.4.1 Validity types: a literature analysis

Although most types of validity are still investigated in several studies, some validity terms have become obsolete in newer editions of the *Standards for Educational & Psychological Testing* [82]. Additionally, it is widely accepted that construct validity is the central theme of validity [83]; and that face and construct validities are the first two fundamental steps of simulator validation [76].

Van Nortwick *et al.*'s 2010 review [84] showed that 60% of reviewed studies that aimed at establishing validity in surgical simulation targeted construct validity [84]. Similarly, a 2014 literature review by Arora *et al.* [79] revealed that, for studies that addressed face, content, construct, or predictive validities for virtual reality simulation training in Otolaryngology, face and content validities were the most common study types representing nearly half the studied publications. Furthermore, they indicate that construct validity is considered the fundamental requirement for assessment and was evaluated in 28% of the reviewed studies. In a more recent review of low-cost (<£1,500) laparoscopic simulators, Li and George [85] considered analyzing and comparing only face validity of the reviewed simulators.

We perform a similar yet more recent investigation of literature, analyzing studies that conducted some form of experiment to establish one (or more) type(s) of validity for a surgical simulation/training platform.

Search strategy

A search on PubMed database [86] was performed for articles published between 1995 – 2017 using the keywords: ("validity" OR "validation") + ("surgical simulation" OR "surgical simulator" OR "surgical trainer"). The search yielded 260 studies.

Inclusion criteria

A study was included in the analysis if it demonstrated the following characteristics: (1) is a journal publication, (2) is in English, (3) has a simulation component, (4) attends to a specific type or domain of surgery, and (5) addresses at least one type of validity (face, content, construct, criterion, concurrent, transfer, or predictive). Discriminate and convergent validities were considered a subtype of construct validity. One hundred and fifty studies were identified to meet the criteria [87-236].

Literature analysis results

Analysis of all 150 articles concluded that 39% (58/150) of the studies addressed construct validity only; 15% (22/151) of the studies addressed face and construct validities; 13% (20/150) addressed face, content, and construct validities; 9% (13/150) addressed face and content validities, and 7% (11/150) addressed face and content validities (Table 1). It can be observed that not all seven validity types are targeted by the literature in the last two decades. The primary types of validity that continue to be addressed and explored by many studies are face, content, and construct validities. These validity types remain perceived reliable to serve as descriptors of both subjective and objective evaluations of surgical simulator/trainer validation.

Table 1. Analysis results for 150 studies that targeted one (or more) type(s) of validity for surgical simulation and/or training.

Validity type(s) addressed	**Count**	**Studies**
Construct	**58**	[87-144]
Face	**13**	[145-157]
Content	5	[158-162]
Concurrent	1	[163]
Predictive	2	[164, 165]
Transfer	1	[166]
Face and construct	**22**	[167-188]
Content and construct	5	[189-193]
Content and criterion	1	[194]
Face and content	**11**	[195-205]
Criterion and construct	1	[206]
Content and concurrent	2	[207, 208]
Concurrent and predictive	1	[209]
Construct and predictive	1	[210]
Face, content, and construct	**20**	[211-230]
Face, construct, and transfer	1	[231]
Face, construct, concurrent, and transfer	1	[232]
Face, content, construct, and concurrent	3	[233-235]
Face, content, construct, convergent, and predictive	1	[236]

2.4.2 Definitions of relevant validity types

As eluded to by many, several definitions of validity have been used and the literature still lacks consensus regarding guidelines for establishing them. However, there are key elements associated with validity types and are described here.

Face validity describes how realistic the simulator appears to the end user or, in the case of a surgical trainer, trainers and trainees [237]. It reflects the simulator's ability to produce a realistic reproduction of the real surgery. This is satisfied by attaining the user's opinion using a structured questionnaire that typically uses Likert scale rating [238].

Content validity measures the simulator's ability to deliver its purpose. A surgical trainer's content validity is established by demonstrating (using user questionnaire) its capacity and utility as a training platform for specified tasks derived from the actual surgery.

Construct validity confirms the simulator's ability to quantifiably differentiate between varying levels of expertise. It can be obtained by incorporating the simulator with a component able to measure concrete aspects of a surgical skill. The typical approach is to expose various levels of expertise (experienced surgeons versus trainees, students, or nonsurgical personnel) to the simulator and observe the generated metrics with the hypothesis that they will correlate with experience level. Several studies emphasized the significance and reliability of such *direct objective metric* measures and many researchers used quantitative performance metrics including completion time, distance traveled, number of mistakes/errors, force applied, and dissection time [81, 239, 240].

2.5 Related Work: Nuss Procedure Simulation and Planning

To date, a real-time surgical simulator and trainer for the Nuss procedure has not been introduced. A patient-specific surgical planner was developed by Rechowicz *et al.* [19, 20] where they developed a generic model of the ribcage as well as a set of patient-specific finite element models (FEM) using CT data from actual PE patients. A force–displacement model was then constructed to train an artificial neural network (ANN) to generalize the data set. Additionally, they described a methodology for assessing the planner's outcomes against information obtained from an average chest shape. However, their work did not include an interactive real-time simulation of the procedure for training and skill transfer.

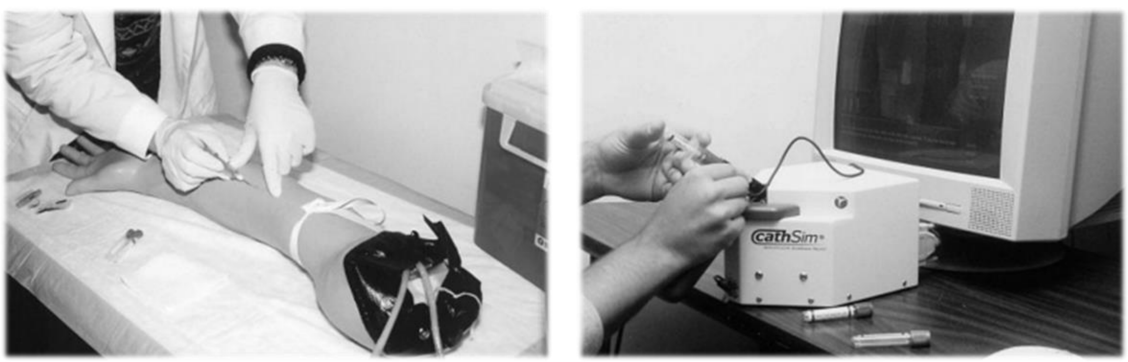
Other groups that explored surgery planning were steered toward studying the biomechanical behavior involved within the procedure [241], simulating stress distribution of the ribcage [242, 243], or otherwise conducting experiments to indicate the existence of a stress distribution difference between children and adults [244, 245]. Collectively, no prior research addressed the development of a real-time surgical trainer for the procedure.

2.6 Related Work: Virtual Reality (VR) VS. Physical (manikin-based) Simulators

In general, surgical simulators fall within a virtuality continuum or spectrum where physical human manikins are on one extreme and virtual reality simulators are on another. In this section, studies that compared and contrasted the implementation of the two schemes for surgery simulation are described with greater focus on those who combined them for an improved result.

2.6.1 Studies that compared identical tasks on VR vs. physical vs. hybrid simulators

Through comparing a virtual reality versus a physical implementation of phlebotomy training simulation, Scerbo *et al.* (2006) indicated that using physical limbs (or a manikin in general) is a better fit for training on tasks involving surface palpation of complex anatomical regions and other merely tactile skills (Fig. 6). On the other hand, they indicated that other cues, such as those which occur in response to user actions, are better reproduced using a VR environment such as blood emission at the incision point [246]. To the benefit of the NPST, their work can be used as a general strategy to guide the classification of surgical tasks and cues into pro-virtual or pro-physical setups.



(a) (b)

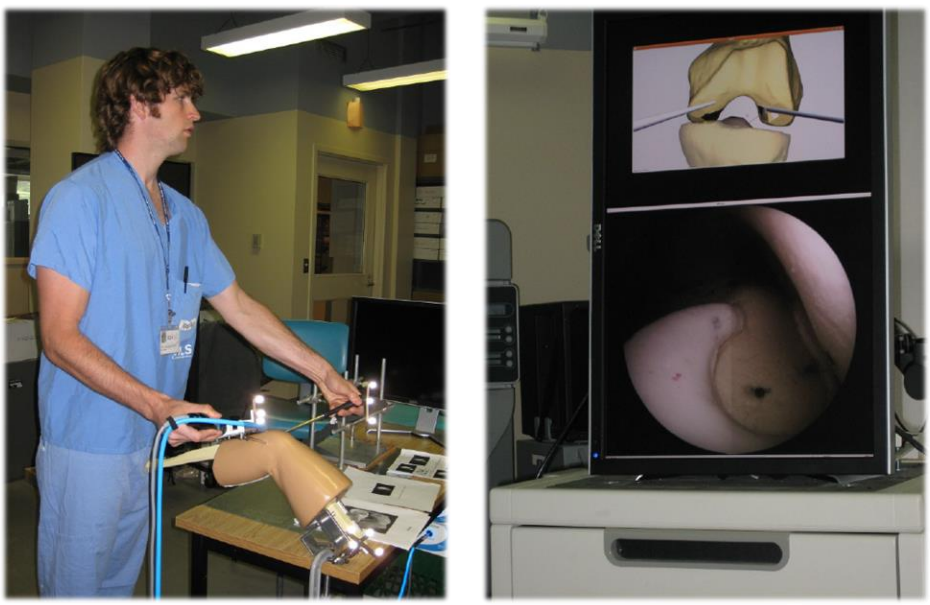
Fig. 6. Trainee performing a phlebotomy on a simulated arm (a) and the CathSim system (b). (Reprinted from [246] with permission. © The Infusion Nurses Society, 2006).

Botden *et al.* (2007) conducted an experiment to evaluate the difference in performance between a laparoscopic virtual reality trainer (LapSim VR) and a hybrid virtual/physical trainer (ProMIS AR). Although they used the term augmented simulation to describe their mixed reality implementation, ProMIS AR incorporates a torso-shaped manikin with an instrument tracking system which synchronizes the motion of the tools in the virtual environment with that of the physical tools affected by the user (Fig. 7). The authors compared aspects such as realism, haptic feedback, and didactic value between the two setups when performing lifting and grasping as well as suturing tasks. They concluded that ProMIS AR is a better training platform than LapSim VR [247] . Their work can be used as a reference for the development of NPST to distinguish between basic tasks that are better performed using a physical or a virtual setup.

(a) (b)

Fig. 7. ProMIS Augmented Reality laparoscopic simulator (a) and LapSim VR laparoscopic simulator (b). (Reprinted from [247] with permission. © Springer, Société Internationale de Chirurgie, 2007).

Li *et al.* (2011) developed a mixed reality simulation for arthroscopic knee surgery. In their system, they used an artificial knee joint coupled with the actual tools and arthroscopic camera used in the surgery. Manipulation of this physical setup influences a synchronized 3D computer generated model of the joint (Fig. 8). Their study showed compelling evidence that the mixed reality setup can assist novice residents in the challenging task of locating anatomical locations in arthroscopic surgery. Although the same outcome was not observed for experienced surgeons, all participants agreed the system provides an accurate representation of the surgical experience [25]. From their conclusions, the same hypothesis will be investigated for the NPST to validate whether it can enhance experts' as well as novices' skills in a comparable manner.



(a) (b)

Fig. 8. Mixed reality simulation for arthroscopic knee surgery: (a) a residents performing a trial and (b) a monitor showing the navigated arthroscopic view. (Reprinted from [25] with permission. © Springer-Verlag Berlin Heidelberg, 2011).

Loukas *et al*. (2012) investigated whether basic laparoscopic skills acquired with a virtual reality simulator (LapVR) are transferable to a standard video trainer (VT) and vice versa (Fig. 9). Their study demonstrates that both types of simulator enhance the performance of novices in a consistent manner. The skills learned on LapVR are transferable to the VT and vice versa. However, for complicated tasks such as knot-tying, two users each training on one of the two modalities will not end up with the same level of proficiency [248]. Their work can be used as another instance for describing areas where a physical setup can be more advantageous over a virtual one, and vice versa. It is also worth investigating whether skills would be transferable between a solely physical and a solely virtual setup of the NPST.

(a) (b)

Fig. 9. VR simulator (a) and VT (b). (Reprinted from [248] with permission. © Springer Science+Business Media, LLC, 2012).

2.6.2 Studies that combined VR and physical simulators to produce a hybrid

Kotranza *et al.* (2008) developed a virtual/physical integration for training on clinical breast cancer examination by augmenting a physical manikin with a collocated virtual human avatar overlaid on top of it using a head mounted display (HMD), allowing the trainee to palpate the physical surface of the manikin which affects the virtual avatar using pressure sensors (Fig. 10). The authors conclude that their system increases communication skills of trainees as their experiment demonstrated that most students readily accepted the tactile modality by naturally using gentle stroking and touching motions based on their feedback [21]. In 2009, the group further expanded their work to incorporate in-situ visual feedback of the user's performance to indicate necessary corrections of palpation by displaying the touch map and the pattern-of-search map in real-time to reinforce learning. In their work, the authors note that manikins provide little feedback on the user's performance, cannot be adapted for patient-specific cases, and are difficult to be incorporated with different scenarios [249]. In the benefit of the NPST, this will steer focus away from attempting to accomplish training evaluation, patient specificity, and scenario introduction from a physical constituent of the NPST.

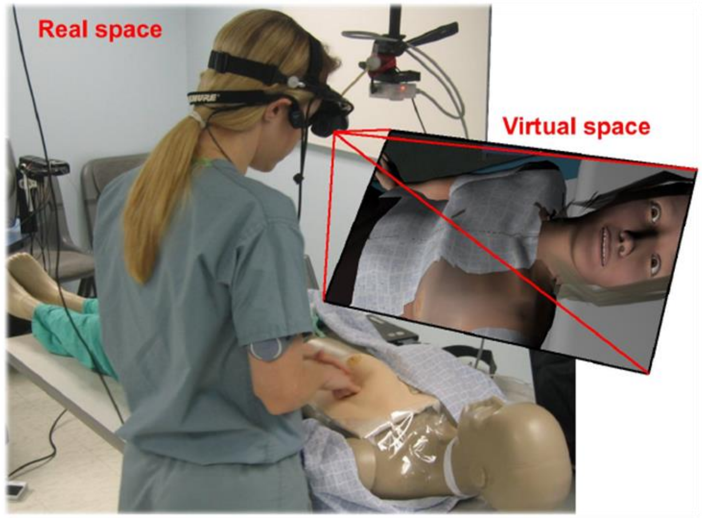


Fig. 10. A mixed reality human merges virtual and real spaces. The user views a VH while touching her physical embodiment, including tangible interfaces. (Reprinted from [21] with permission. © IEEE, 2008).

Halic *et al.* (2010) introduced a mixed reality simulation framework for the rasping task in the artificial cervical disc replacement (ACDR) procedure. Their system couples a plastic model of the spine with a virtual environment. As the user manipulates the real surgical tools to perform the rasping task, an optical motion tracking system (Vicon) captures the motion and, as a result, the binocular stereoscopic display shows the synchronized interaction on the virtual models (Fig. 11). The authors report that the developed simulator was tested by five different physicians who indicated that it is effective enough to teach anatomical details of cervical discs and is able to convey basics of the ACDR surgery and rasping procedure [250]. Their work will be used in the development of the NPST merely for guiding separation of tasks into pro-physical and pro-virtual ones. Tool tracking will be compensated for in the NPST using the haptic device eliminating the need for motion capture.

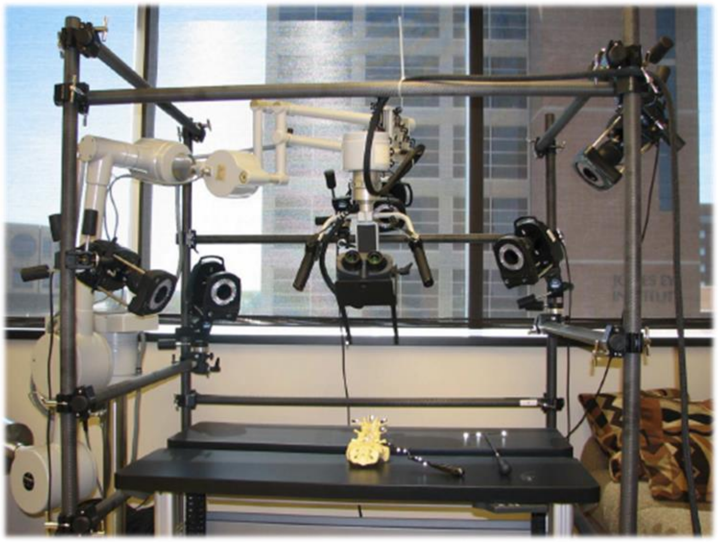


Fig. 11. AR setting: Five VICON cameras on the bars, stereoscopic binocular display mounted binocular headgear. Plastic spine model and curette are placed within the tracking volume. (Reprinted from [250] with permission. © Halic and Kockara; licensee BioMed Central Ltd, 2010).

Several years ago, a research group at the University of Virginia developed a virtual reality simulator that utilizes force feedback to train the cognitive and motor tasks involved in the tube thoracostomy (chest tube insertion) procedure (Fig. 12 (left)) [22, 23]. Subsequently in 2010, English *et al.* of the same group sought to improve the user's sense of presence of the existing chest tube insertion trainer by incorporating the VR system with a chest manikin (Fig. 12 (right)). Their design performs a breakdown of the procedural tasks to allocate which is better implemented using a virtual implementation, and which using a physical one. Their improved system aimed to use the strengths of each element of simulation to provide an optimal experience with an increased degree of immersion, a higher authenticity of the simulator, and better skill transfer of joint psychomotor-cognitive tasks. Through the development of their system, the authors provide a very relevant indication while attempting to simulate one of the tasks. They note that, in a VR environment alone, the user cannot experience a sufficiently authentic reproduction of a tunneling sensation and finger constriction that mimics the sensory response of entering the patient’s chest cavity using currently available haptics technology [24]. Their work serves as a very comparable platform for the NPST as it describes computational constraints of a solely virtual reproduction of the simulation and motivates a hybrid iteration of the system. Additionally, their work is considered very relevant as it involves tool tracking using a haptic device and the main task of the procedure involves tool insertion with a fixed pivot.

(a) (b)

Fig. 12. Fully virtual tube thoracostomy simulator (a) and developed hybrid simulator (b). (Reprinted with permission from [22, 23] © IEEE, 2008; and from [24] © IEEE, 2010).

Carbone *et al.* (2011) described a method to develop a patient-specific training platform for abdominal surgery with a hybrid approach. This hybrid approach involves using silicone models of abdominal organs augmented with electromagnetic tracking sensors to allow for deformations and coupled them with a corresponding virtual environment (Fig. 13). The authors utilize medical images to generate 3D models for the virtual environment using segmentation as well as to produce molds for synthetic silicon organs. Although only a simple deformation for the stomach is implemented, the system was evaluated by clinicians who confirmed a high degree of realism [251]. Their work is highly relevant and beneficial for the NPST in case a calibration and alignment of physical and virtual organs and behaviors proved to be required in the simulation.

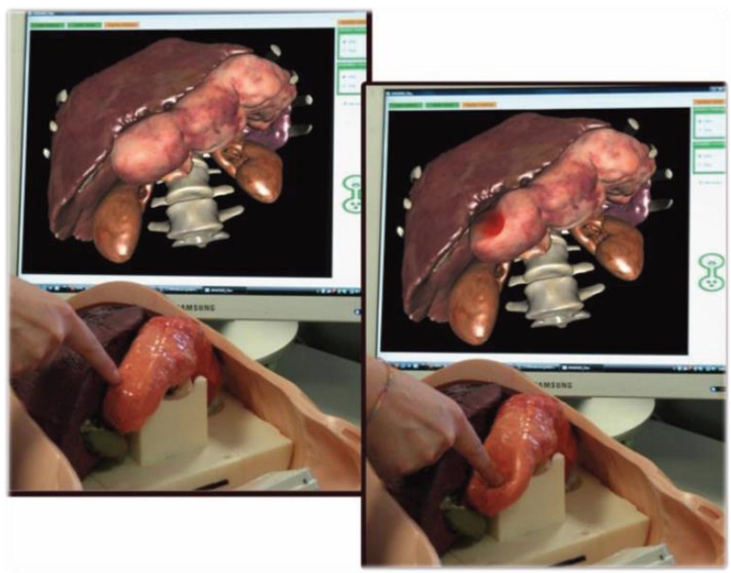


Fig. 13. Example of real time deformation of the virtual environment. The stomach is highly deformed so in virtual it is highlighted in red to underline the extent of deformation. (Reprinted from [251] with permission. © Carbone and Ferrari, 2011).

In 2013, Larnpotang *et al.* [252] at the University of Florida presented a mixed reality simulator using physical exteriors augmented with a virtual environment for training on central venous access (CVA). The physical component was produced via 3D printing and includes the torso, neck and head of a manikin providing anatomical landmarks such as a palpable sternal notch, clavicle and ribs (Fig. 14 (left)). The internal organs and soft tissues were virtually modeled using medical image segmentation and were registered to the physical component with sub-millimeter accuracy (Fig. 14 (right)). The user can puncture the skin using the surgical instrument (needle) which is coupled with a 6 degrees of freedom (DOF) magnetic sensor fitted inside the needle bore providing real-time tracking. The authors also implemented an automated scoring algorithm to measure the performance of the training session. The simulator was evaluated by vascular surgeons who indicated that the system is beneficial as a training and educational tool.

(a) (b)

Fig. 14. Mixed simulator of central venous access. (a) Physical components including physical syringe and needle, and (b) their virtual counterparts. (Reprinted from [252] with permission. © IEEE, 2013).

Later that year, Bova *et al.* (2013) of the same group described three different simulators for neurosurgical procedures that employ a combination of physical and virtual components to provide the user with essential visual and haptic cues: a ventriculostomy simulator (Fig. 15 (a)), a radiofrequency lesion (RFL) probe insertion simulator for the treatment of trigeminal neuralgia (Fig. 15 (b)), and a spinal instrumentation simulator (Fig.

15 (c)). The three simulators use a physical external model (head, skull, and spine, respectively) coupled with an electromagnetic tracking system that is collocated with a virtual model allowing the user to use the actual surgical tools to perform skin cutting, tool/needle insertion, drilling, burr hole creation, and instruments fixation. The virtual components of the three simulators render the relevant internal anatomies such as brain ventricles, fluoroscopic view of the trigeminal verve region, as well as spinal radiograph, respectively [253, 254]. The same group is currently developing similar mixed-reality systems for pediatric procedures. Their simulations are considered very relevant for the NPST as they all involve tool insertion of some sort. Their tool tracking mechanism will be studied for potential benefits.

(a)

(b)

(c)

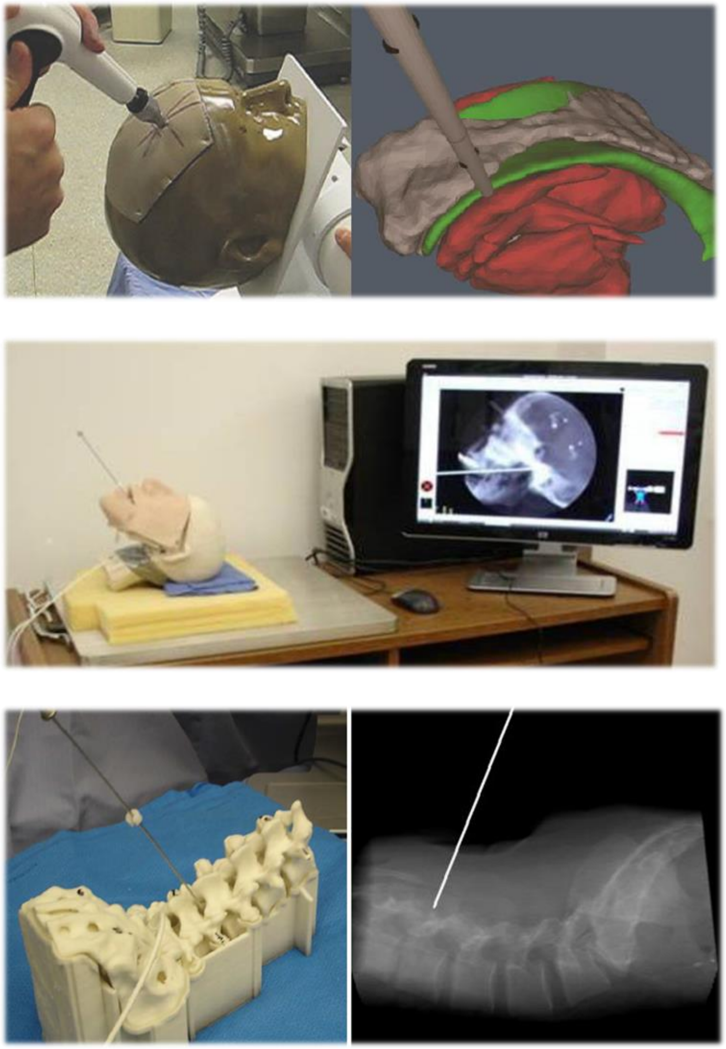


Fig. 15. Physical (left) and virtual (right) components of (a) the ventriculostomy simulator, (b) the radiofrequency lesion (RFL) probe insertion simulator for the treatment of trigeminal neuralgia, and (c) the spinal instrumentation simulator. (Reprinted from [253] with permission. © Oxford University Press, 2013).

Hochman *et al.* (2014) found it beneficial to combine a physical printed model of the temporal bone with a virtual haptic soft tissue rendering to construct a hybrid temporal bone surgical simulator. The authors augmented the end-effector of a HD^2 haptic device

[255] to hold an otic drill used in the simulation. The printed bone model consists of two drillable layers separated by a free-space, within which a virtual spring force model is applied by the haptic interface increasing the force with penetration depth (Fig. 16). The physical model is collocated with the virtual one to trigger different types of forces [256]. This is another study relevant to tool tracking for the NPST as they perform that using the haptic device. Additionally, their system necessitates physical and virtual worlds calibration and alignment to trigger the correct types of forces at the right time and location.

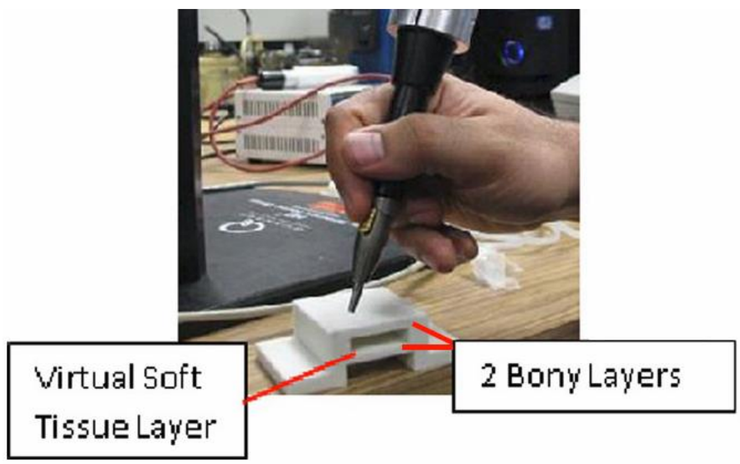


Fig. 16. Developed Mixed reality model showing HD2 haptic device, otic drill, and gripper assembly. (Reprinted from [255] with permission. © Hochman *et al*., 2014).

2.7 A Framework for Surgical Simulation: Virtuality and Interactivity

In this section, a simulation framework for evaluating the utility of virtual versus physical platforms for surgery is introduced. It also considers the different degrees of user-system interactivity that can be utilized. This framework can serve as a continuum to classify hybrid surgical simulators and identify their characteristics.

The approaches followed by research groups in the studied literature showed that the attributes that affect the user's sense of presence can be classified by two elements: *degree of virtuality* and *degree of interactivity*. Consequently, a 2-dimensional *Continuum for Hybrid Surgical Simulators* can be constructed to demonstrate a classification system (Fig. 17). In a generic sense, any hybrid surgical simulation environment can be characterized with a location on this model.

The degree of virtuality relates directly to the virtual-physical continuum discussed in section 2.3, where a hybrid trainer falls between two extremes of a virtual-physical spectrum. Purely virtual or purely physical training platforms would fall close to the far left or the far right of the continuum, respectively. With this rationale, for a system to be considered a hybrid, it must not be placed too close to either extreme of the virtuality dimension.

The degree of interactivity refers to the presence of multi-way (active) or a one-way (passive) interaction between the system and the user [257]. In an active system, several forms of user/system interaction are present where the user can affect the system in more than one manner. A multi-way interaction is also achieved by incorporating multiple forms of feedback from the system to the user either by using visual implications of the user's actions displayed on a monitor; or by incorporating haptic feedback, where the user can sense the collision or interaction with organs when maneuvering the surgical tool using a haptic device; or a combination of both. A system where the user affects the virtual environment through both a haptic device as well as a physical manikin for instance; or a system that provides both visual and haptic feedback corresponding to the user's behavior would be placed higher on the active/passive dimension.

For instance, an active (involving two-way interaction) hybrid system discussed earlier is the tube thoracostomy trainer developed by English *et al.* [24] (2010), where a haptic interface is incorporated to simulate the sensation of tube insertion. A multi-way interactive arthroscopy trainer (Simbionix's Arthro Mentor™) allows the user to control the surgical tool with a haptic device as well as adjust the posture of a physical model of the knee; and observe the implication of both in the virtual environment [66].

An example of a hybrid system that provides one form of feedback to the user (less active) is the work by Kotranza *et al.* (2008) for clinical breast exam training [21, 249] discussed earlier, where physical palpation on the manikin is transformed in to visual feedback displayed on the visual interface, but no sensory information is fed back to alter the components of the physical manikin accordingly, or in the form of force feedback that the user is able to perceive. Such a system would be placed in the middle of the active/passive dimension.

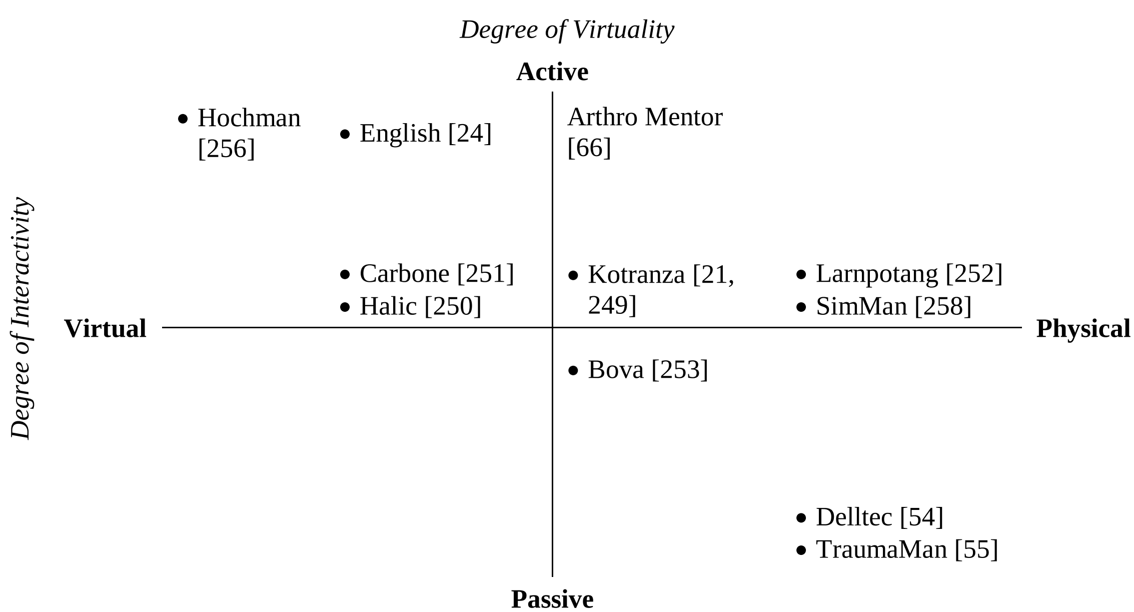


Fig. 17. Continuum for hybrid surgical simulators.

2.8 Considerations for a Hybrid Surgical Trainer

There are several aspects that must be considered when developing a surgical simulator/trainer that is composed of virtual and physical components. This section discusses the two main aspects relevant for hybrid surgical training platforms and refers to related work discussed in the previous sections.

2.8.1 Synchronization

Coupling of virtual and physical modalities necessitates that corresponding interactions are highly synchronized. As typical in a hybrid system, a user affects a physical component and observes the effect on a virtual environment. Therefore, issues such as latency, coordinate systems alignment, and synchronized visual/haptic cues are of tremendous significance. The degree of said coupling is very impactful since unsuccessful synchronization of virtual and physical components highlights and emphasizes the artificial nature of the environment. Studies discussed in section 2.5.2 showed the significance of this seamless coupling to improve psychomotor and cognitive tasks. This is also true for systems with passive physical objects as demonstrated by [25] for arthroscopic knee surgery.

2.8.2 Fidelity

Surgical simulators/trainers vary greatly in terms of fidelity ranging from primitive synthetic objects inside boxes or hemispheres aimed at Fundamentals of Laparoscopic Surgery (FLS) training to high fidelity manikins capable of breathing, blinking, and replicating human vitals on a computer system. Although the level of fidelity of a trainer undoubtedly influences the user’s degree of immersion and sense of presence, it doesn’t necessarily determine the degree of validity of the trainer nor its effectiveness as a training platform. The degree of fidelity should, therefore, be governed by the scope of training and the skills to be emphasized [259]. Increasing fidelity in components that correspond to features not directly related to the tasks of interest makes for an inefficient simulation platform.

CHAPTER III

A FULLY VIRTUAL NUSS PROCEDURE SIMULATOR

As mentioned before, this work aims to fulfill the need for a Nuss procedure simulator for training and skill transfer. In this chapter, the development of one of the two investigated simulation platforms is carried out following a modality that corresponds to the fully virtual extreme of the virtual-physical continuum described in section 2.3 of this dissertation. The developed system described in this chapter will be referred to, throughout this work, by the fully/solely virtual Nuss procedure surgical simulator, the virtual NPST, the virtual setup/modality/scheme, or the purely virtual version, interchangeably.

A frequent practice to simulate the behavior of the surgical tool around the pivot for laparoscopic procedures is via a physical port. In this fully virtual setup, however, the insertion behavior is simulated without utilizing physical constraints. The intent is to solely utilize virtual components to, subsequently, be contrasted with a physical implementation.

The methods undertaken to develop this system were derived from the requirements of the actual procedure. The workspace of the simulator and the anatomical structures of the virtual environment as well as the behaviors and physics-based interactions were constructed to fulfill realism and fidelity of the simulation. A haptic interface was integrated with the system to achieve a reproduction of surgical tool manipulation. Additionally, a patient-specific model of the chest and PE deformity were reproduced to allow for different training scenarios. The work described in this chapter about the fully virtual Nuss procedure simulator has been reported in several publications [27-29, 260].

Following the discussion of the methods, the outcomes and results are reported and a discussion of the merits and limitations of such an implementation is provided.

3.1 Methods

In this section, the approaches used to develop of a solely virtual patient-specific Nuss procedure trainer are outlined and discussed. The methods used to reproduce relevant aspects of the surgery are described and the user interface is detailed.

The virtual Nuss procedure simulator was constructed integrating a 3D Systems (6 degrees of freedom motion / 3 DOF force) Phantom Premium 1.5 high force haptic feedback device [261] with an anatomically-correct virtual environment. A thorough description of the approaches used to develop the system's components is provided here.

3.1.1 Interface

The user interacts with the virtual environment and controls the surgical tool using a haptic interface. The haptic device's specifications are 0.007 mm (3784 dpi) nominal position resolution, 37.5 Newtons (8.4 lbf) maximum exertable force, and 6.2 Newtons (1.4 lbf) continuous exertable force. As explained in [27, 28], a dynamic link library (DLL) was developed to interface with the Geomagic® OpenHaptics® Toolkit [262] and import parameters from its application programming interface (API) to the environment developed on the Unity engine [263].

To reproduce the actual setup from the operating room, two views/displays are constructed to simultaneously provide an external view of the patient's avatar and an internal thoracoscopic view, respectively. The external view of the patient is displayed on an LCD and projected on a mirror and the internal thoracoscopic view is displayed on a separate monitor. Both views are coupled with the surgical tool's consistent motion as the user moves the haptic device's stylus. A Wiimote (Wii Remote™) [264] is used to provide the surgeon with control of the thoracoscopic camera in real-time. It is critical to maintain a high update rate in the haptic force servo loop to prevent any force discontinuities; therefore, the haptic interface and the simulation run asynchronously (Fig. 18).

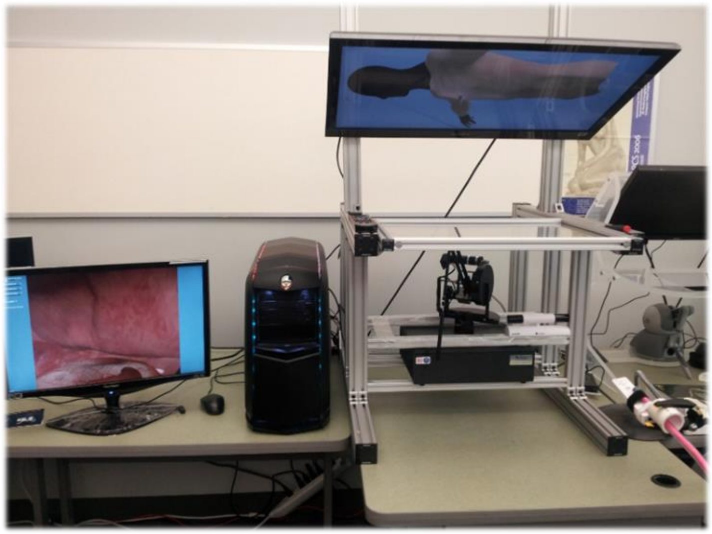
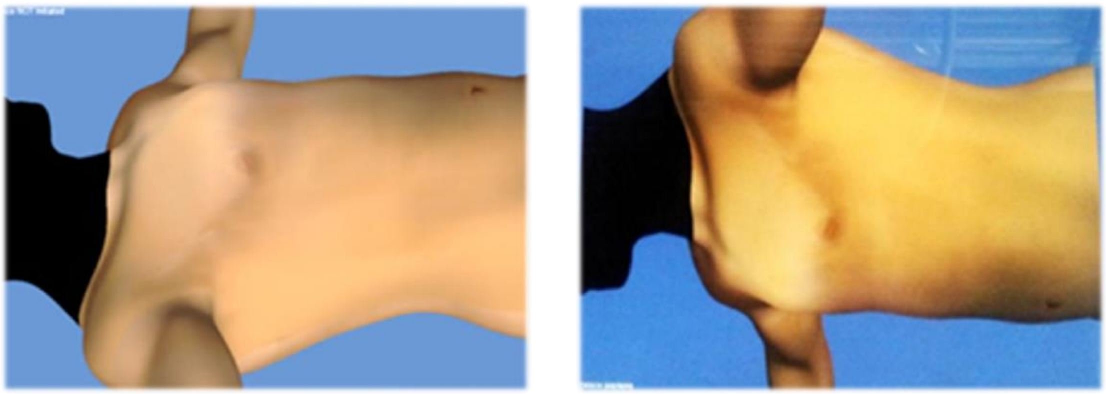


Fig. 18. Hardware setup for the fully virtual Nuss procedure simulator.

3.1.2 Graphics and camera configuration

The integration of the virtual environment with the haptic interface calls for a method to achieve collocation (consistency) between the two. A mirror's behavior leads to a horizontally flipped view of the patient's avatar and, therefore, should be compensated for (Fig. 19). In order to correct this behavior while preserving the properties of the graphical scene, an adjustment of the external view takes place independent of the thoracoscopic view. In the graphics pipeline, after the geometric primitives are modeled into the required objects and transformed into a common world coordinate frame (world space), the objects are transformed from the world coordinate system to the view reference (camera) coordinate system. The product of that is the Model-View Matrix. The next stage is to project the view onto the projection plane where the 3D coordinate system of the camera is transformed into the 2D coordinate system of the image space of the screen. The projection transformation is performed by multiplying the Model-View Matrix by the Projection Matrix (P).



(a) (b)

Fig. 19. Original image of the scene (a) and its corresponding image in the mirror (b).

Since the external view's scene is flipped in the *y*-axis, a customized projection operation is constructed to control the rendered direction when transforming from the camera coordinate system into the coordinate system of the screen. Utilizing a customized Projection Matrix gives access to manipulating the projection direction as desired. To obtain a new *customized Projection Matrix* ($\hat{P}$), the original Projection Matrix (P) is multiplied by a 4×4 matrix that has a negative *y*-component as shown in Equation (1).

$$\hat{P} = P \times \begin{pmatrix} 1 & 0 & 0 & 0 \\ 0 & -1 & 0 & 0 \\ 0 & 0 & 1 & 0 \\ 0 & 0 & 0 & 1 \end{pmatrix} \tag{1}$$

In the graphics architecture, however, back-facing polygons are conventionally not visible in the scene and only front-facing polygons are visible. By convention, all polygons whose vertices appear in a counterclockwise order are called front-facing. When the projection is flipped in the *y*-direction, its counterclockwise order of vertices becomes clockwise which turns the polygon into a back facing polygon that will not be rendered. Fig. 20 demonstrates this phenomenon for a polygon *abc*. This will take place using the new customized Projection as all polygons of the external view are rendered as back-facing and therefore are not visible. In the industry standard for high performance graphics OpenGL® application programming interface (API) [265], the rule of choosing front-facing polygons can be changed using the function *glFrontFace()*. A similar approach was implemented in the application of the surgical simulator for the external view only to resolve the issue. A thorough discussion of this approach was reported by Obeid *et al*. in [266].

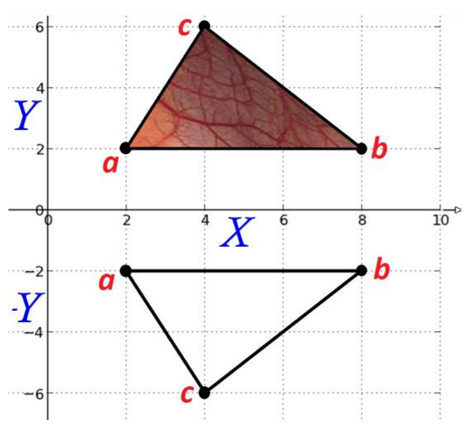


Fig. 20. Triangle *abc* and its image mirrored in the *y*-direction.

3.1.3 Thoracoscopy

A very important aspect of the simulation is to give a surgeon the ability to interact with a surgical space resembling the actual procedure. In reality, the thoracoscope is typically placed one or two intercostal spaces below or, less often, above the insertion point of the surgical tool. The entry point of the thoracoscope is modeled as a stationary point with constrained translation in all axes. The thoracoscope can slide in its local *z*-direction through this stationary point in and out of the thoracic cavity. Typically, the surgeon does not operate the thoracoscope during surgery. Therefore, the simulator is constructed to work in two modes: (1) the thoracoscope camera automatically follows the tip of the introducer or (2) it can be fully controlled by the same or another user. In the second mode, the orientation of the camera is controlled by a Wiimote's pitch, roll and yaw [264]. The camera is a child of the Wiimote's pivot, which simulates the position of the thoracoscope's trocar. Due to the limitations of the Wiimote's accelerometer, yaw cannot be directly detected. Therefore, the setup was supplemented by adding the Wiimote's sensor bar which provided this necessary information.

3.1.4 Modeling anatomical structures and surgical instruments

Sophisticated 3D modeling platforms were utilized to design the models of the surgical tool (introducer) as well as the anatomical structures of the patient's body with appropriate and realistic surfaces and textures. Following is a description of the techniques used to model these components.

For the *torso*, a generic low polygon model was used and adjusted to a posture that corresponds to demographics of PE patients. A skeletal model created by [267] based on

Visible Human Project [268] was used to construct the geometry of the *ribcage*. Since the *internal intercostal muscle* is observed to take the shape of adjacent ribs and the sternum, cloth modeling was used coupled with directional forces to bring the *internal intercostal muscle* model in contact with the ribcage. The model of the *internal intercostal muscle* has, correspondingly, deformed to take the shape of the ribcage allowing the *ribs* and *sternum* to be distinguishable in the thoracoscopic view. The *pericardium* was modeled based on an anatomical atlas.

The *mediastinum* was modeled by, firstly, creating a volumetric capsule model. Boolean subtraction and intersection modeling was then used to omit a specific portion of the model subtracting the part intersecting with the pericardium in a way that both models fit without gaps. Generic models of the *lungs* and the *diaphragm* were acquired from a repository for 3D-models.

The main tool used in the Nuss procedure (the *introducer* by Biomet Microfixation [41]) is shown in Fig. 21 (a). One of three sizes: S, L and XL which differ in curvature can be used, depending on the patient's size. Models of the three sizes of the introducer were constructed based on orthogonal photographs (Fig. 21 (b)).

(a) (b)

Fig. 21. Surgical instrument: (a) introducer and (b) 3D model created for the introducer.

3.1.5 Texturing of 3D models

In coordination with the surgeons and with the appropriate approval from the institutional review boards (IRB) of Old Dominion University (ODU), Eastern Virginia Medical School (EVMS), and The Children's Hospital of the King's Daughters (CHKD), numerous images and videos were using the thoracoscope during the Nuss surgery were collected and organized to construct a digital image database for relevant anatomical organs and surfaces. The author has acquired the necessary clearance to be present at the operating room on several occasions to observe the procedure and supervise the acquisition of the necessary footage from real surgery.

After the 3D models composing the virtual environment are created, a process of UV mapping is carried out. In this process, each of the 3D models is unwrapped along seams (Fig. 22 (a)) to create an editable 2D map describing the coordinates of the unwrapped 3D model. The coordinates of this mesh are then relaxed and edited to become more suitable to receive a texture (Fig. 22 (b)). Parallel to that, appropriate images from the database were cropped (Fig. 22 (c)), edited and modified to be used as raw texturing material. Using image editing techniques, this raw material is used to create interactive brushes that are then used to carefully paint the UV-map for the corresponding 3D model, resulting with an unfolded texture map (Fig. 22 (d)). This map is then enhanced and modified to be coupled with a bump map to add realism to the appearance of the simulated torso, ribcage, internal intercostal muscle, diaphragm, lungs, pericardium (Fig. 22 (e)), and mediastinum.

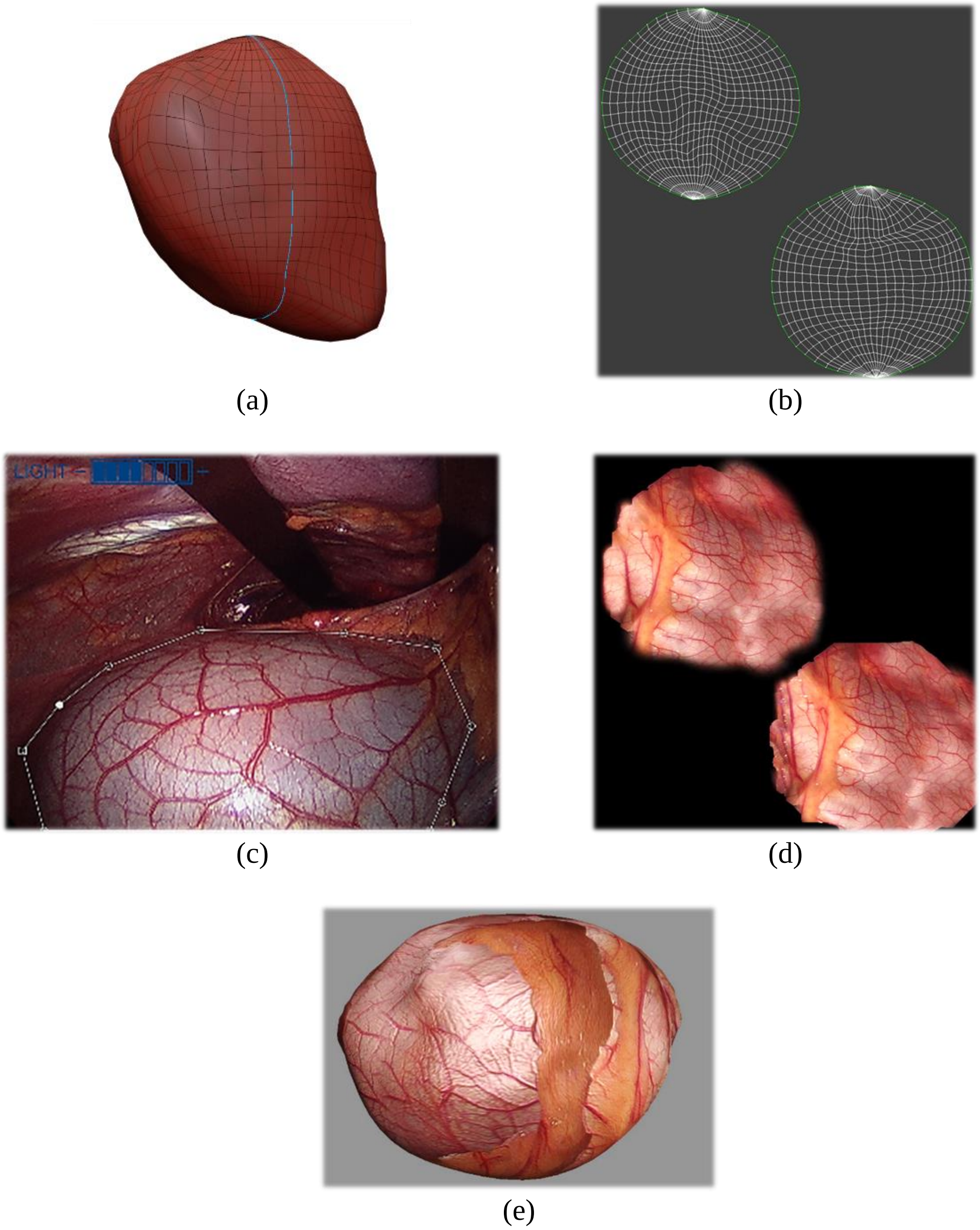


Fig. 22. Texturing: (a) 3D model of the pericardium with seams, (b) corresponding modified UV map, (c) source image cropping, (d) textured UV map, and (e) textured model.

3.1.6 Haptics and pivot mechanics

A haptic interface allows the user to interact with component of the virtual environment. Capabilities of the haptic device are utilized to provide the limited field of motion and the constrained nature of the surgical tool's movement, similar to what occurs in the actual surgery.

As explained in more detail in [27], the *pivoting* behavior of the tool at the insertion point (Fig. 23) can be approximated using a fully virtual setup utilizing forces from the haptic device; the haptic device acts as a virtual pivot constraining the tool from motion in the local *x*- and *y*-directions by applying high stiffness forces while allowing translation in the *z*-direction only. The *z*-direction motion is along the axis of the tool at the point of the pivot allowing further insertion. This absence of force in the *z*-direction is altered depending on the orientation of the haptic device's stylus, i.e., the movement is allowed in the local *z*-direction of the stylus which is reoriented in real-time when the stylus is rotated. Light friction force is applied in the local z-direction when moving through the pivot to simulate friction generated between the tool and the skin at the insertion area. To apply such accurate forces in all the corresponding haptic device local axes, global force components are to constantly be converted to local force components as follows:

1. Get current rotation matrix R.
2. Get total displacement vector, d, between initial and current positions.
3. Multiply R by d to get the local translation vector t_L.
4. Multiply t_L by scaling vector $< 1, 1, 0 >$ to get new local translation vector t_{LS}.

5. Multiply inverse of rotation matrix, R^{-1}, by t_{LS} to get force components in the local coordinates of the haptic device.

Fig. 23. Schematic of the surgical tool's advancement into the thorax maintaining a stationary pivot [269].

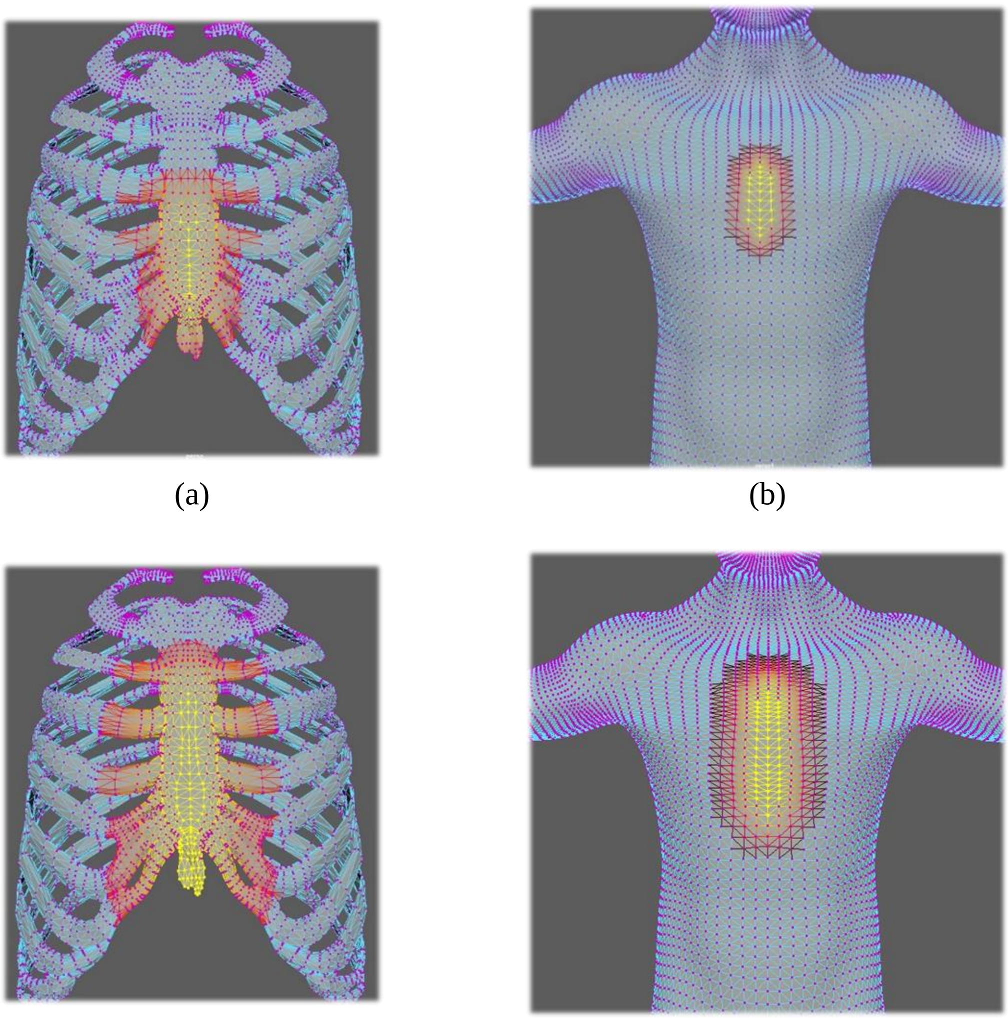
Collision with surrounding organs is incorporated since inadequate dissection may cause severe damage, such as penetrating an organ with the introducer's tip. In the case collision is detected when inserting the tool, a new stiffness force based on the penetration depth is generated in the local z-axis. This force depends on the elasticity of the colliding organ; however, it is assumed to be the same for all organs. A variation of stiffness and friction coefficient values were tested by experienced Nuss procedure surgeons at CHKD to approximate the sensation of the tunneling behavior.

In case a collision occurred due to a rotational motion of the introducer, a similar approach can be followed if a 6 degrees of freedom (DOF) of force haptic device is used. Such an implementation was incorporated and tested. However, if using a 3-DOF of force haptic device, only translational forces can be applied and there is no capability to simulate forces caused by rotation around the pivot. In this case, the movement of the surgical tool is visually disabled once in collision to prevent the tool's mesh from intersecting with any other mesh while the physical tool is in motion.

3.1.7 Patient-specific PE deformity

The virtual NPST was incorporated with a patient-specific parameterized representation of the PE deformity. The purpose was to construct a system where parameters that describe the morphology are obtained from CT scans and used as input to a modifiable simulation of PE. Pre-surgical surface scans of the chest were collected using a non-radiological laser surface scanner (FastSCAN) [270] from patients with PE just prior to the Nuss surgery (*EVMS IRB#* 07-08-EX-0202). Pre-surgical CT and post-surgical X-rays were collected for each patient to complement the database built for validation purposes and to obtain the ground truth as described by [260]. Each subject's deformity was classified by cup, saucer or unknown, as well as symmetric or asymmetric criteria. For this work, patients characterized with symmetric deformities were chosen, which resulted in two patients with cup morphology and four patients with saucer morphology.

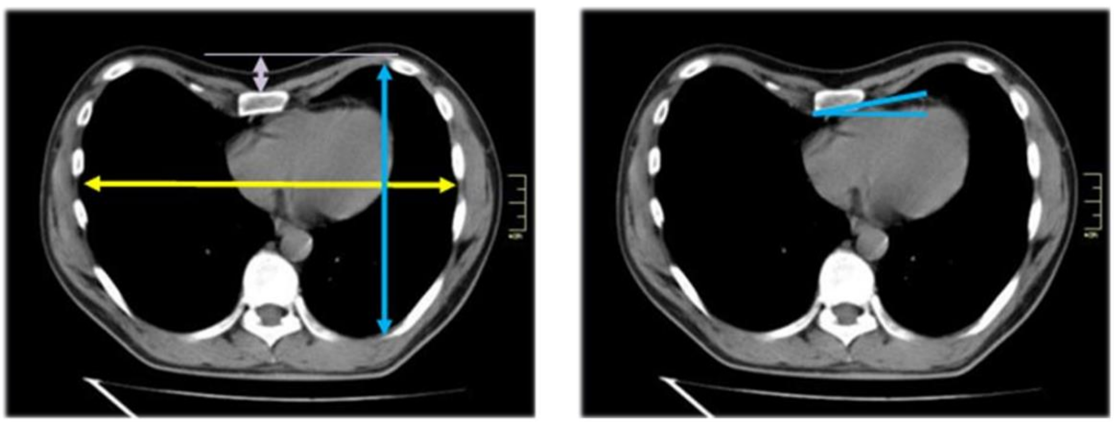
A system of morphed deformations with a parameterized falloff was incorporated into the anatomical entities affected by PE, namely the 3D meshes of the torso (skin), internal intercostal muscle, and ribcage. These deformations are governed by an underlying bone-system embedded into the sternum to simulate PE deformity. This approach is widely used for character animation. The movement of the bone-system of the sternum affects, correspondingly, the envelopes (areas of influence) of the linked 3D meshes. Vertices within the area of influence for each mesh are assigned gradual weights to produce smooth transitions upon movement. A separate envelop of influence was modeled for each of the entities and the weights assigned followed characteristics of both morphology types introduced by [34] and available via the CT data collected: cup and saucer. As can be seen in Fig. 24, vertices within the influence envelope do not receive equal deformation weights as weights fall off rapidly for the cup type morphology (Fig. 24 (a and b)) while follows a Sigmoid function for the saucer (Fig. 24 (c and d)).



(a) (b) (c) (d)

Fig. 24. Deformation influence envelopes for a cup type PE for (a) the ribcage and (b) the torso; as well as a saucer type PE for (c) the ribcage and (d) the torso.

To develop a patient-specific system, parameters that describe both the overall shape of the chest as well as the PE morphology must be specified. Information that describes the *width* and *depth* of the ribcage as well as the amount of pectus *depression* and *torsion* are obtained from the CT slice that displays the deepest depression (typically the slice used to calculate the Haller index [37]) (Fig. 25). Using information pertaining to slice thickness and number of slices that cover the height of the sternum, a coefficient of scaling for the height of the entire ribcage can be approximated ($\text{height} = \#\text{ of slices } \times \text{slice thickness}$).



(a) (b)

Fig. 25. CT measurements: (a) width, depth, depression, (b) sternal torsion

To define patient-specific PE deformation, it is essential to specify parameters for measurement that can be quantified and used to accurately reproduce the morphology and govern the developed morphed deformation system. One parameter that describes the morphology is *depression*, which is a measure of the distance between the ribs-line and the position of the sunken sternum taken from the CT layer where the rest of the parameters are measured (Fig. 25 (a)). For the *depression* parameter, simply measuring the deepest point of the sternum in the CT image will produce an error. This error is demonstrated by observing a sagittal view of the sternum as shown in Fig. 26.

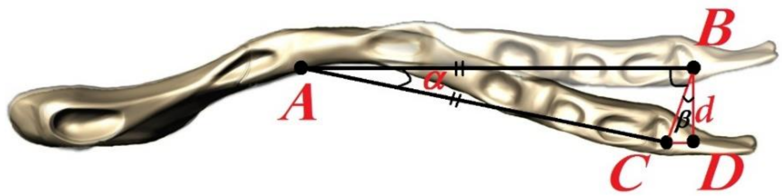


Fig. 26. Calculation of depression parameters

To address this error, we define the axis of a normal sternum to be the line AB and the axis of a deformed sternum to be the line AC both of length a. Connecting the two lines with line BC results in an isosceles triangle ΔABC. The angle $\angle CAB$ is that of sternum depression which is the measure that we need as the bone and envelop for the ribcage model can be deformed by rotation. We will call this angle α.

The CT image, however, only provides a transverse view which means that when a linear measurement is made, it gives the length of line BD which we will define as the linear distance of depression d. A mathematical operation is needed to convert this linear distance to an angle. In addition, merely using this calculated angle for depression assumes that the depression results in a vertical drop of point B which means that, since the sides AB and AC are of equal and fixed length, points C and D are in the same point in space. This is not true. Another step will, therefore, follow to compensate for that difference.

First, the value of angle α is to be estimated given the linear distance of depression d. To do so, the isosceles triangle ΔABC is considered. In order to find the value of α, we assume temporarily that BC is equal to BD. The error produced by this assumption will be compensated for in the following step. Using the Law of Cosines, we can come to:

$$d^2 = AB^2 + AC^2 - 2 * AB * AC * \cos\alpha \tag{2}$$

Which gives:

$$\alpha = \cos^{-1}\left(1 - \frac{d^2}{2a^2}\right) \tag{3}$$

After determining the value of the angle α, this information can be used to calculate the actual length of the side BC, which we will call $\hat{d}$, by considering both ΔABC and ΔBCD. From ΔABC, the angles of the triangle are related as follows:

$$\angle ABC + \angle ACB + \alpha = 180^{\circ} \tag{4}$$

Since $\angle ABC = \angle ACB$,

$$\angle ABC = \frac{180^{\circ} - \alpha}{2} \tag{5}$$

Therefore,

$$\beta = \frac{\alpha}{2} \tag{6}$$

Using this result in ΔBCD,

$$\cos\beta = \frac{d}{\hat{d}} \tag{7}$$

which gives

$$\hat{d} = \frac{d}{\cos\beta} \tag{8}$$

We then use the new value $\hat{d}$ to calculate the depression angle α. This value of the angle will be used as the *depression* parameter. Another parameter for deformation is the sternum torsion which can be simply measured from the CT slice used as it shows the amount of torsion that the sternum undergoes (Fig. 25 (b)).

Thus, the patient specific information collected in the previous steps are shape parameters including *width*, *length* and *depth* as well as deformation parameters including *depression* and *torsion*. To deploy these values to the patient's avatar in the simulation, the environment was constructed to receive them as input parameters. Applying the shape is performed as scaling factors for the model in the *x*, *y* and *z*-dimension. For the deformation parameters, the value of depression is inputted by the user which is then internally converted to the angle α, as well as the value for the sternal torsion. This input affects directly the bone system that controls the morphed deformation envelopes to simulate a patient-specific deformity. This work was published in [260].

To evaluate the patient-specific model, it is implemented for the 6 patients utilizing parameters measured from their pre-surgical CT scans; and the outputs from the patient-specific model are compared with the pre-surgical surface scans for each patient. The results of this evaluation are presented in a form of a color map in section 3.2.2.

3.1.8 Simulation and interactions

In this section, the dynamics related to the real-time deformations of the organs and components of the body are constructed and the interactions of the surgical tool with the environment is explained.

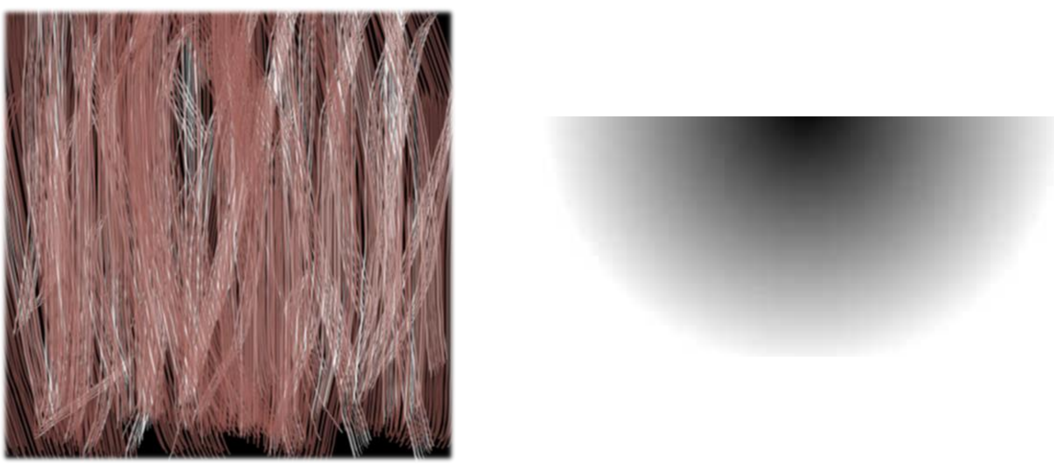
Beating heart

Physics-based interactions were modeled to deliver realistic behavior of the pericardium, which plays a crucial role for the actual and simulated procedure. To simulate the beating heart, a non-uniform scaling deformation of the pericardial sac was constructed to reproduce systole and diastole motions. The two-stage cycle is performed based on a heart rate of 70 per minute, which can be adjusted as desired. The systole motion occupies 30% of the timeframe, while diastole motion occupies the other 70%; this behavior adds realism to the beating heart. The beating of the heart is linked to real-time instead of animation making the heart motion independent of the speed of the machine. In many instances of PE, the pericardial sac is depressed by the sternum and pushed to the left side of the thoracic cavity. This behavior was modeled by squeezing the anterior part of the pericardial sac (translating the vertices of that area posteriorly) according to the *depression* parameter. As the *depression* parameter is increased or decreased, the squeezing is changed with the same ratio. The pericardial sac is also pushed laterally to the left as severity increases.

Mediastinal dissection

Through spectating real surgery, the mediastinal dissection process starts with the surgeon pawing down on the anterior part of the pericardium and stretching its tissue to reveal a “foamy” plane. The surgeon then continues this motion while advancing the introducer forward to the left side of the thorax. Collision-based deformation is performed between the introducer collision mesh and an organ’s mesh. These collision-meshes are constructed from the original rendered mesh of each organ. Although computationally expensive, we attempt to utilize this method as well as using shaders to simulate mediastinal dissection.

Once collision is detected with the surgical tool, the mediastinum model is deformed in a similar fashion to other organs. The difference is that it does not return to its initial shape after collision (plastic deformation). A dynamic plane (sprite) is placed at the point where the surgeon chooses to make the pathway. This plane is textured with a texture map representing the “foamy” or “webby” structure (Fig. 27 (a)) with an underlying transparent channel to reproduce the creation of a hole in the mediastinal plane. Instead of creating an actual hole, a shader is used turn specific pixels of the sprite resembling the foamy tissue transparent, according to a semicircle-shaped gradient (Fig. 27 (b)) that is masked on the sprite.



(a) (b)

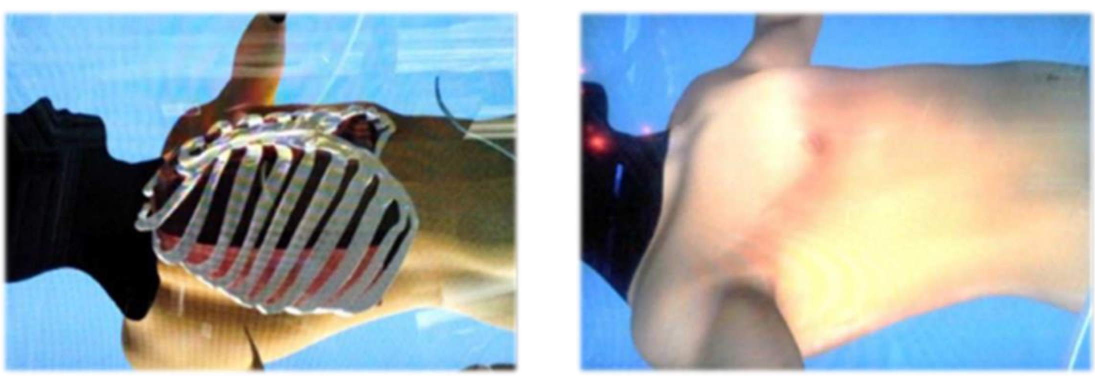
Fig. 27. Model of the stretched mediastinum (a) and the mask with gradient (b).

3.2 Results

The adopted methods were implemented in the game engine Unity and the simulation components were executed. Close supervision and feedback of experienced surgeons throughout the development process assisted in delivering a realistic reproduction of the procedure. This section presents the results obtained and describes the outcome of the used techniques.

3.2.1 Mirrored-image correction

To correct the mirrored image problem, programming was used to construct a Customized Projection Matrix ($\hat{P}$) used to un-flip the projection of the scene. Furthermore, the back-face determination criterion was inverted to ensure rendering all polygons after this change in projection (Fig. 28 (a)). As a result, when running the simulation, the correct view of the graphical scene is displayed on the mirror (Fig. 28 (b)).



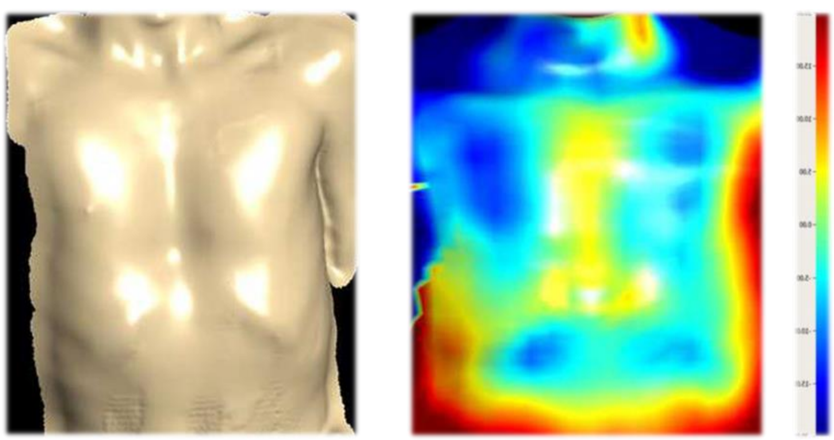
(a) (b)

Fig. 28. Graphical image in mirror using ($\hat{P}$) before (a) and after (b) addressing the back-facing polygons issue.

3.2.2 Modeling PE deformity

To evaluate the ability of our generic model to conform to the patient's size and deformation, we compared the patient-specific generated deformity with the actual shape of the patient's chest (ground truth) in the form of a 3D mesh obtained using surface scanning (Fig. 29 (a)). The comparison of the two surfaces was carried out utilizing Delta™ Surface Comparison Utility from ARANZ Scanning Ltd (ASL) [271].

Fig. 29 (b) shows results of such a comparison for the cup type PE. In this case, the difference between the surface scan (Fig. 29 (a)) and simulated chest shape (Fig. 30) along the centerline is slightly above 0 and equal to approximately 4 mm. The slight difference in the lower rib region can be explained by error introduced by breathing or by differences in supine postures from one patient to another. However, the differences in the deformity region are close to 0. The differences recorded indicate satisfactory approximation with minor inaccuracies. The maximum difference is very localized and situated in the area below the xiphoid process inferior to the region of interest.



(a) (b)

Fig. 29. Pre-surgical (a) cup type PE surface scan and (b) comparison between simulated and actual chest shape.

Fig. 30. External view of the patient avatar model with simulated PE condition.

3.2.3 Simulation of the mediastinal dissection

A mediastinal tunnel can be created using the simulated surgical tool. Fig. 31 (a) illustrates the initial position of the introducer at the start of the simulation. At this point, the introducer is constrained by high stiffness forces in local *x*- and *y*-axes and friction force in the local *z*-axis preventing from any rapid movement. The forces reach approximately 6.2 N, which is the maximum nominal force of the haptic device. The force coefficients were estimated with collaboration of experienced Nuss procedure surgeons from CHKD. The produced behavior approximates the movement of the tool around the pivot and the forces involved.

Once the tool is in contact with that part of the mediastinum, the mediastinum deforms revealing the webby tissue (Fig. 31 (b)). Upon further motion, the hole increases in diameter (Fig. 31 (c)). As the introducer advances to the other side of the mediastinum (Fig. 31 (d)), the tool pushes away the surrounding tissue and the friction force is increased as the introducer comes into contact with the mediastinum. This force was approximated to not exceed 0.5 N, depending on velocity of the tool's motion. Reaching the other side of the thoracic cavity requires creating another hole in the mediastinum (Fig. 31 (e)). Once the tip reaches the other side, the mediastinal tunnel has been created (Fig. 31 (f)). Organ-specific collision forces with deformable objects are not simulated.

The next step requires reorienting the thoracoscope so that the surgeon can look underneath the deformity and can identify a blue sphere which marks the exit point from the thoracic cavity (Fig. 31 (g)). The simulation ends once the surgeon touches the blue sphere without causing any complications (Fig. 31 (h)).

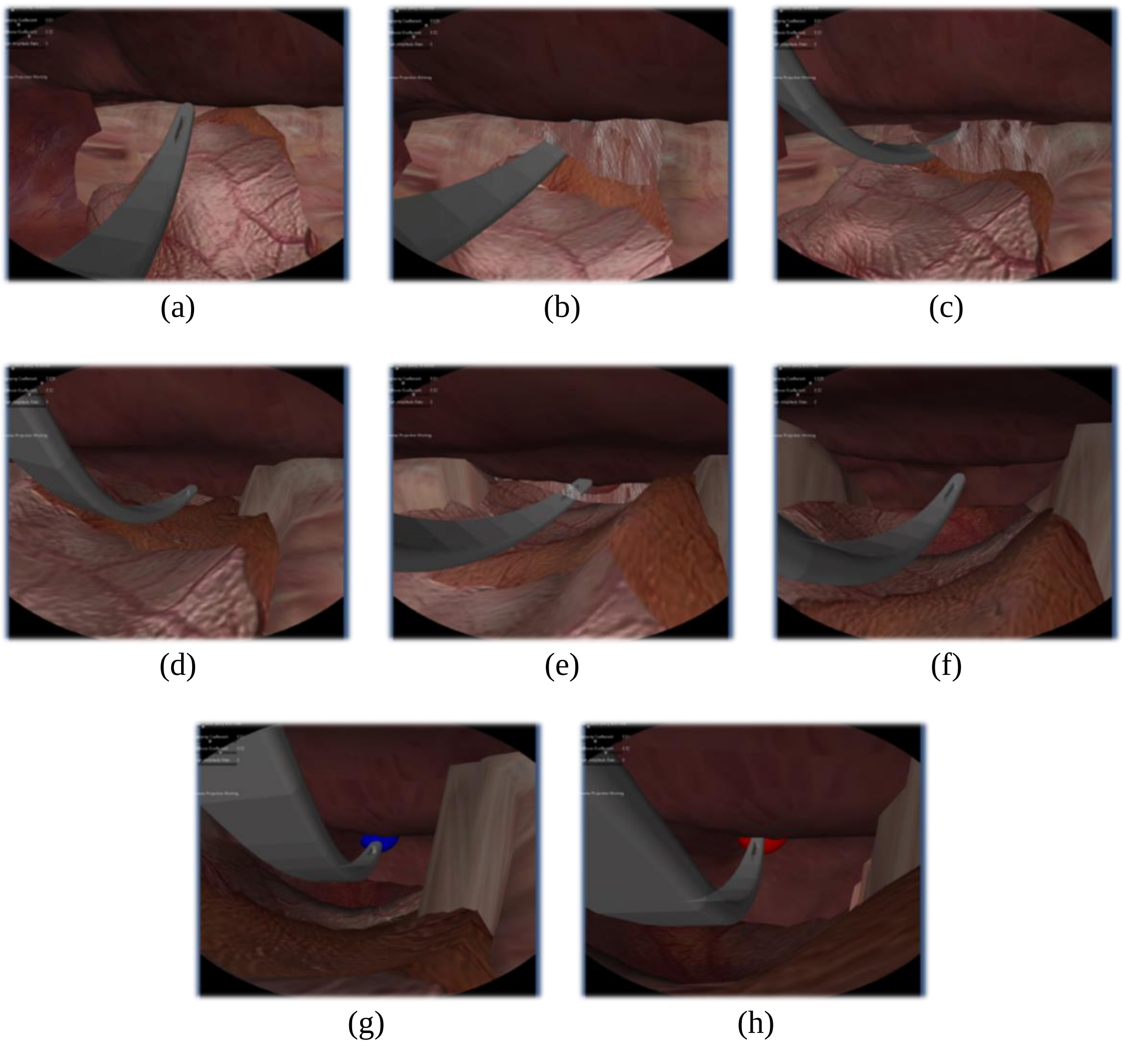


Fig. 31. Simulation of mediastinal dissection in the fully virtual NPST.

3.3 Advantages and Limitations of a Fully Virtual Simulation

The fully virtual NPST provides a reasonable approximation of the procedure and a realistic training platform. However, it suffers from several limitations. Its merits and limitations are discussed here.

This virtual implementation of the procedure displayed strength for patient-specific simulation where dimensions and parameters describing the patient's torso and deformity are extracted from CT data to, consequently, tailor the simulated models. Furthermore, the virtual environment allows for introducing surgical scenarios and complications to the procedure for training as well as for the ability to integrate dynamic behavior such as heart beating and bleeding. Another benefit is the ability to accurately reproduce forces with the aid of the haptic device and associated physics-based models. It is also an automated environment that can potentially be used to monitor and measure the user’s performance.

On the other hand, given the nature of a generic (3-DOF) haptic device's end-effector, no insertion mechanism can be performed without moving the stylus' natural pivot along. Therefore, although the force models for constraining the haptic device's motion and simulating collisions are a successful approximation of the tool's pivoting behavior, a discrepancy is present because of the lack of physical constraints and an insertion capability, where the end-effector is always carried along causing the stylus' physical joint to be located, at some instances, at coordinates that correspond to the inside of the patient. The virtual implementation of the simulator also lacks visual cues such as an exterior visualization of intercostal spaces as well as tactile cues, both of which are important for training. It is also not, or at least not easily, possible in such setup to utilize the haptic device to operate instruments such as a bar flipper, Kelly clamp, and umbilical tape.

CHAPTER IV

A FULLY PHYSICAL NUSS PROCEDURE SIMULATOR

In parallel to the development of the fully virtual simulator platform described in the preceding chapter, a manikin-based fully physical counterpart was explored. In this chapter, the methods adopted to construct a Nuss procedure training manikin are described. The approaches for designing, prototyping, and assembling the physical components that make up the simulator are articulated. A similar critique of this modality is then provided where the advantages and limitations are laid out.

The setup described in this chapter corresponds to the fully physical extreme of the virtual-physical continuum described in section 2.3 of this dissertation and will be referred to, throughout this work, by the fully/solely physical Nuss procedure surgical simulator, the physical NPST, the NP manikin, the physical setup/modality/scheme, or the purely physical version, interchangeably.

4.1 Methods

In a fully physical version of the simulator, rapid prototyping, 3D printing and form casting techniques are utilized to create a physical manikin-based simulator of a patient's torso with a PE deformity.

4.1.1 Interface

The Nuss procedure training manikin allows the user to become familiar with main aspects of the surgery. The user can train on the actual surgical tools including the pectus introducer, pectus bar, retractors, Kelly clamp, stabilizers, and umbilical tape (Fig. 32).

Furthermore, the user can perform initial sternal elevation which is becoming a routine part of the procedure. The surgeon uses a bed-mounted crane, such as a Rultract® system [44], to perform lateral or subxiphoid elevation of the sternum before mediastinal dissection. This component of the surgery has proven to assist tremendously in decreasing the effort required to create the pathway through the mediastinum.

Through this interface, the user is also able to utilize visual and tactile cues relevant for characterizing the deformity and making decisions regarding insertion and exit points.

Fig. 32. Real surgical tools from the surgery can be used for training on the NP manikin.

4.1.2 Thoracoscopy

To display the internal view of the manikin, two approaches were implemented. The first prototypical approach uses an inexpensive endoscopic camera (webcam) mounted on a steel rod and inserted into the manikin and manipulated by the user. The camera connects to a computer and uses that connection to provide necessary lighting during usage.

In a second, more advanced approach, an actual Stryker laparoscopic tower [272] was integrated with the manikin including the light and power sources as well as both a 5 millimeter- and a 10 millimeter-size autoclavable laparoscopes. The user is, thus, able to use the same scope used in the real surgery.

4.1.3 Synthetic skin, external intercostal muscle, and organs

Two iterations of a PE-deformed ribcage were developed. In the first iteration, a proof-of-concept design of the ribcage was constructed by modifying the skeletal model from the Visible Human Project [267, 268] to create a 3D model of a deformed ribcage (Fig. 33 (a)). Special pins were modeled for each rib to make it attachable to an 80/20 [273] stainless steel rail (Fig. 33 (b)). The ribs and corresponding pins were then 3D-printed and mounted on the apparatus. A hinge was inserted into the 3D-printed sternum to allow for anterior and posterior articulation. A second iteration of the ribcage was constructed by acquiring a generic thorax anatomy skeleton model (Fig. 33 (c)).

For the external intercostal muscle and the skin, Smooth-On synthetic material [274] was utilized to prepare and shape a multi-layered and -colored skin as well as a strong yet elastic rubber mesh placed between the skin and the ribcage to resemble the external intercostal muscle (Fig. 34 (a, b)). Synthetic material was also used to form cast models of the pericardium, lungs, and diaphragm that each differ in elasticity and pliability (Fig. 34 (c, d, e)).

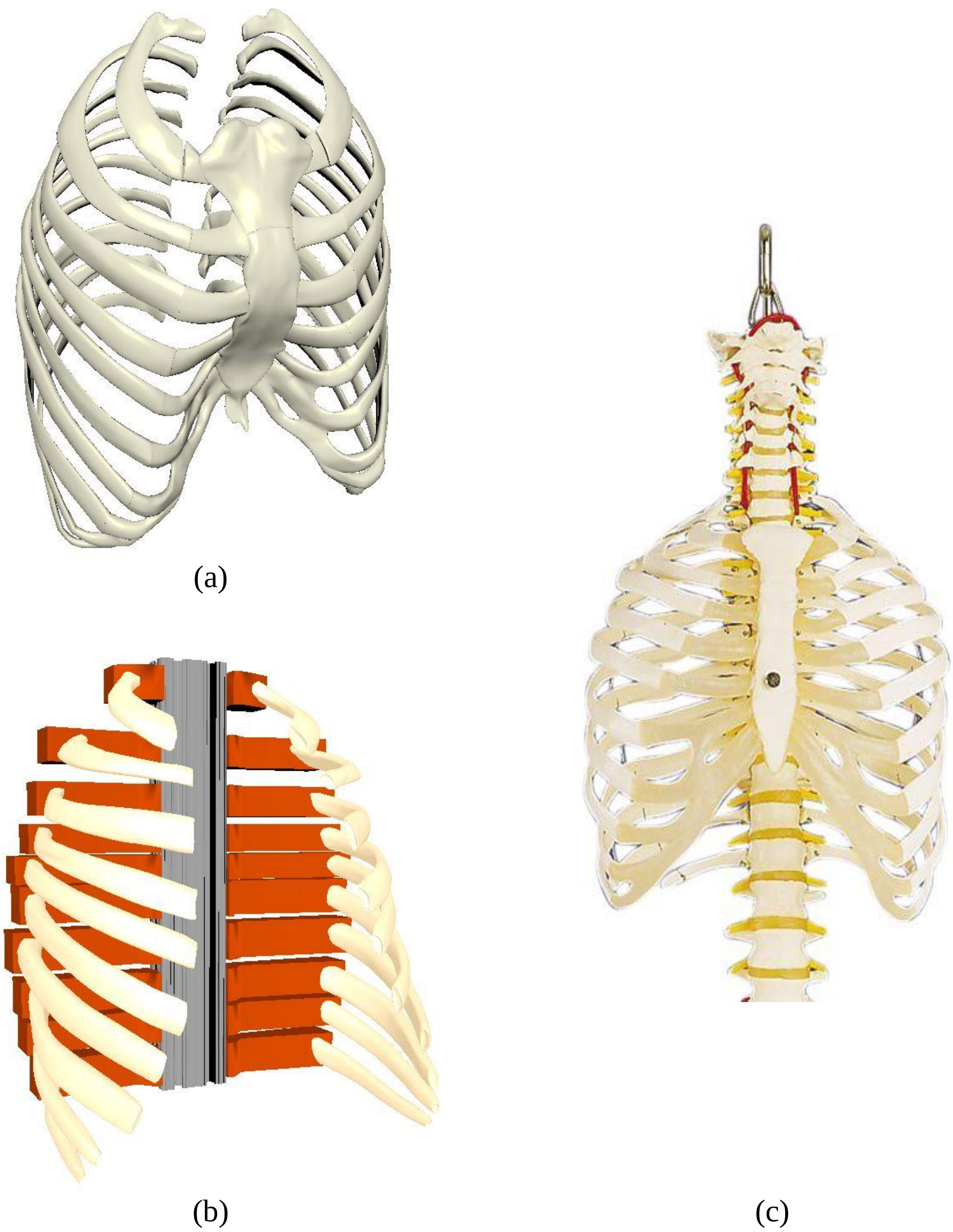
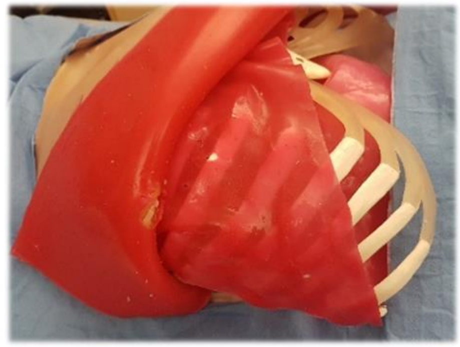


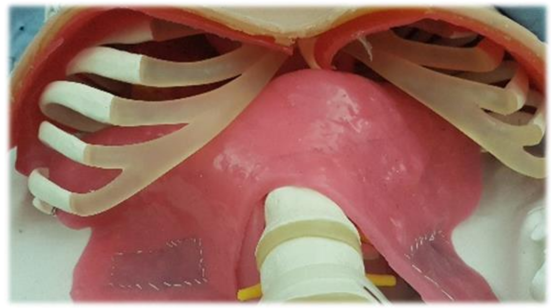
Fig. 33. Ribcage construction for the Nuss procedure manikin. First iteration using (a) a modified Visible Human Project ribcage model with a PE deformity and (b) the design of 3D-printed ribs mounted on steel rail. Second iteration using (c) a generic anatomy model of the skeleton.

(a)



(b)

(c)



(d)

(e)

Fig. 34. Components of the Nuss procedure manikin constructed from synthetic materials: (a) multi-layer skin, (b) ribcage covered with external intercostal muscle, (c) form casted pericardium, (d) diaphragm model, and (e) the appearance of all the components including the lungs.

4.1.4 Pectus excavatum deformity

Pectus deformity was reproduced on both iteration of the ribcage. The 3D printed model was originally designed with an embedded PE deformity before printing (Fig. 33 (a)). As for the iteration that utilized a ribcage obtained from a generic anatomical skeleton, high-temperature air was applied to the rubber material that resembles the costal cartilages and the sternum was pulled posteriorly to add the PE deformity. In both cases, springs were added to hold down the sternum while allowing the user to elevate it using appropriate techniques from the surgery (Fig. 35).

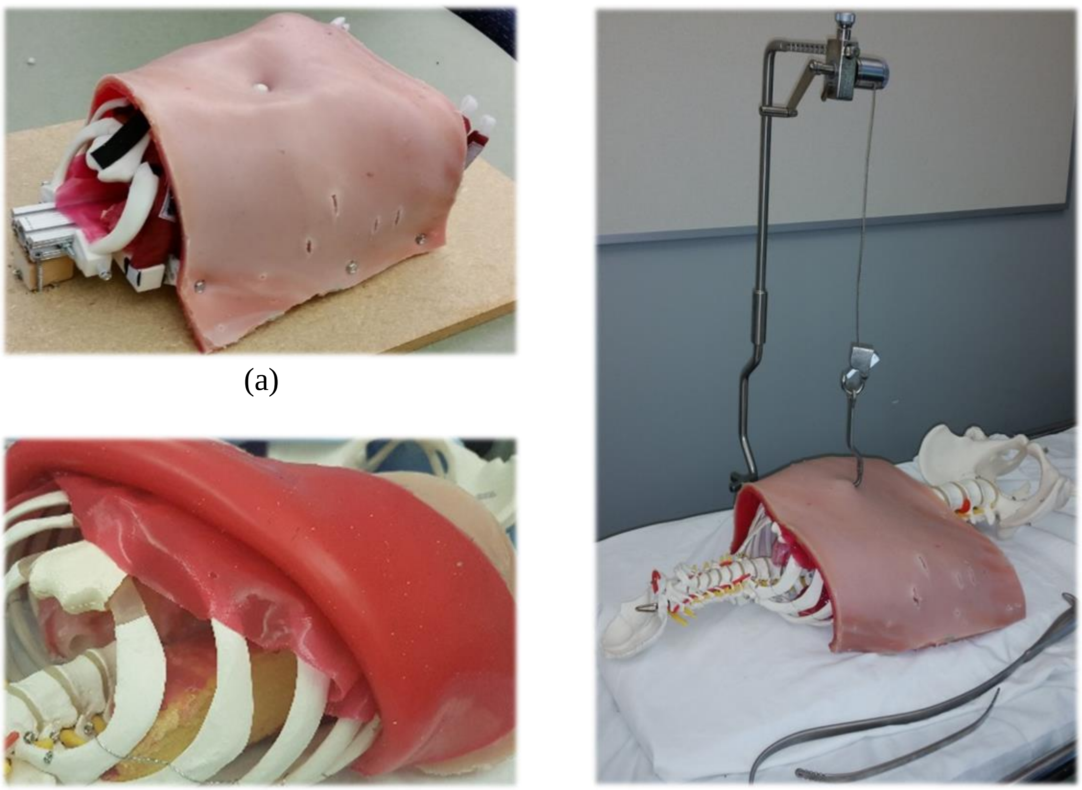
Fig. 35. Springs holding down the sternum to simulate PE deformity.

4.2 Results

The physical NP simulator's components described above provide a platform for training on the real tools from the surgery. Replaceable patches of the synthetic skin and muscle allow for repetitive training (Fig. 36). The manikin makes training on the skills described in the following sections possible.

4.2.1 Initial sternal elevation

Using either a retracting device such as the Rultract® for lateral or subxiphoid sternal elevation (Fig. 36 (c)) or using the Vaccuum Bell system [40], the user is able to train on elevating the sternum to improve the thoracoscopic view of the mediastinum. This is a vital step that impacts greatly the mediastinal dissection process. The manikin is a suitable environment to observe the effect of this step and realize its significance (Fig. 36).



(a) (b) (c)

Fig. 36. The two iterations of the NP manikin components using a prototyped 3D-printed ribcage in one iteration (a) and a generic anatomy model of the ribcage in another (b) as well as using the Rultract® for sternal elevation (c).

4.2.2 Introducer maneuver, tissue dissection, and thoracoscopy

Using the real introducer from the operating room (Fig. 37), the user is able to train on the motions associated with the mediastinal dissection process by pawing with the posterior part of the introducer on the pericardium model and making way to the other side of the chest. This is guided with simulated thoracoscopy as the user observes the internal view of the manikin on the computer and is able to operate the thoracoscope (Fig. 38).

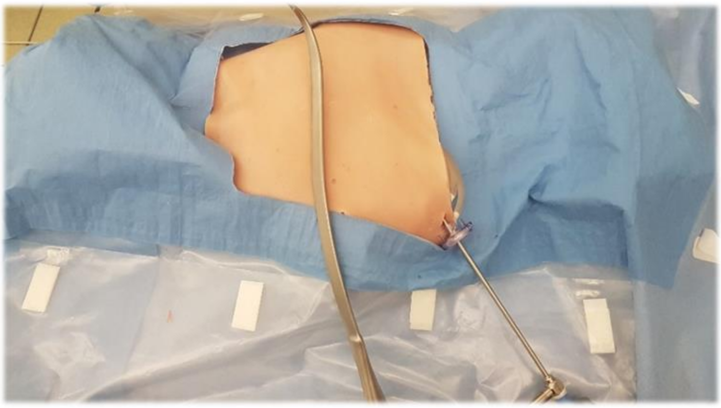


Fig. 37. Real introducer and thoracoscope used for training on the fully physical Nuss procedure simulator.

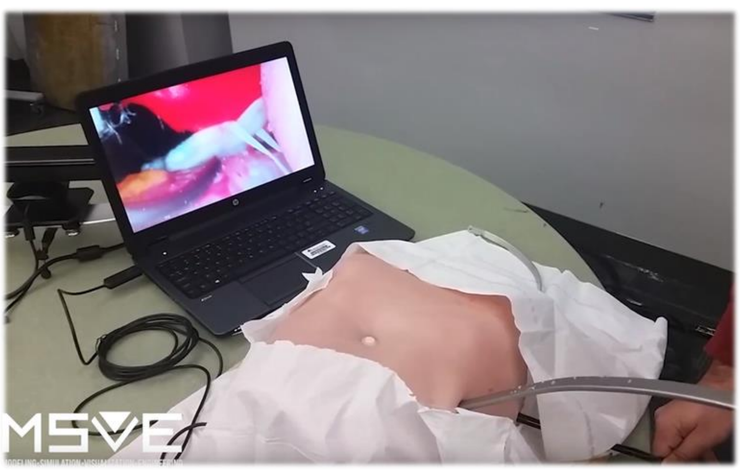


Fig. 38. Thoracoscopic view of the interior of the Nuss procedure manikin.

4.3 Advantages and Limitations of a Fully Physical (Manikin) Simulator

The physical setup clearly adds value to tasks that require the use of surgical instruments where fine movements are expected such as making an incision, creating a suture and securing the stabilizer. The reproduction of the mechanical behavior and pivoting motion of the surgical tools are flawless here as they, the tools, are inserted into the manikin just like they are in the actual surgery. Additionally, not only does the physical setup provide the user with visual cues regarding the external landmarks such as the intercostal spaces, deepest point of depression, and introducer's progress in the subcutaneous tunnel, but also the ability to determine their location in a tactile manner.

In a physical setup, however, no real-time dynamics and interactions are present such as the beating heart, fluid emission, and the complication of puncturing the pericardium. Although these can be added with some difficulty and expense, the system is also unable to introduce procedural complications and pre-modeled scenarios to the simulation which makes the training scope and resolution somewhat limited. Furthermore, this setup is not an efficient platform for patient-specific planning as it requires an offline, and a rather long, changeover. Therefore, an average or standardized set of parameters that describe the patient and deformity populations are assumed to suffice.

CHAPTER IV

A HYBRID SYSTEM

This chapter introduces the ultimate proposition of this work, namely a training platform for the procedure that integrates the better elements of the two simulators developed and discussed in the preceding two chapters. The *hybrid Nuss procedure surgical trainer* (NPST) utilizes an optimal combination of the components of each implementation to produce a mixed-reality system that incorporates necessary physical constituents with a tailored virtual environment. The system described in this chapter will be referred to, throughout this work, by the hybrid Nuss procedure surgical trainer (NPST), the hybrid simulator, the hybrid model, the hybrid setup, or the hybrid version, interchangeably.

The chapter discusses in its outset a thorough task breakdown and analysis of the Nuss procedure performed with consultation of experts who perform the surgery regularly. The purpose of this breakdown is to provide a systematic comparison reference that determines the extent to which a particular simulation modality accomplishes the most relevant characteristics of the surgery. This breakdown segments the surgery and identifies its discrete components for a successful NPST and, subsequently, classifies the procedure’s steps into tasks and subtasks as well as determines their significance for positive training. The two developed simulation modalities are then compared against relevant criteria derived from the nature of the surgery to highlight the potentials and emphasize the limitations of each setup and inspire a hybrid model that combines the best of both. An identification of various aspects in the previous systems that can be improved and/or supplemented with a better approach is detailed.

After delegating each aspect of the surgery to either a virtual or a physical simulation modality, the development of the hybrid surgical trainer is thoroughly discussed. The hybrid NPST's architecture is described and details about its various components are elaborated. In addition to addressing and implementing several upgrades that improve the fidelity and performance of the trainer, a demonstration of how the system fulfills the discussed training requirements is provided.

5.1 Evaluating Previous Systems Against the Procedure

In collaboration with surgeons who frequently perform the Nuss procedure and have pioneered its training and advancement at the Nuss Center [275], a task breakdown of the surgery was performed to identify and classify the discrete steps involved in the procedure and highlight those that are considered most essential for a proposed training platform, i.e., unique to the Nuss procedure. This has, subsequently, identified the scope of the NPST to include the aspects of the procedure that experts consider a priority for training and excluded surgical steps that are trivial or mutual with other procedures. The resulting tasks are shown in Table 2 along with a brief description of how they are simulated on the purely virtual versus on the purely physical platform. To identify areas where each of the two implementations contributes more significantly, the efficient and more realistic implementation of the two is highlighted using bold text.

Consequently, these surgical steps can be translated into a number of training requirements to be present in a successful trainer for the procedure. These requirements are listed in Table 3 as well as whether they are present in each of the two implementations.

As can be observed in Table 3 a virtual setup of the trainer plays a significant role in automated user assessment and patient-specificity aspects. The virtual nature of the simulation allows for tailoring the patient’s avatar and PE deformity to conform to parameters from patient CT data, introducing surgical scenarios and complications to the training scope, as well as enhancing the realism of the experience through dynamic visualizations such as breathing, bleeding, and heart beating. However, the nature of the haptic device hinders the use of various surgical tools and retractors and introduces a discrepancy in the tool’s pivot mechanics as addressed by Obeid *et al*. in [30].

The physical setup of the trainer, on the other hand, adds undisputable value in aspects such as realistic tool mechanics and behavior (bar flipper, Kelly clamp, suture needle, retractors, and umbilical tape), visual and tactile cues involving anatomical landmarks, as well as intuition and ease of use. As it relates to scenario versatility and training scope, however, the physical setup suffers from a cumbersome changeover between uses and a need to settle for an average standardized shape, morphology, parameters, and user experience.

Table 2. Implementation of the Nuss procedure trainer against relevant surgical tasks. The corresponding more efficient and realistic implementation is highlighted in bold.

#	Task	Steps	Purely Virtual Approach	Purely Physical Approach
1	*Interface*	a. Surgeon uses thoracoscopy. b. Surgeon uses scalpel, introducer, and retractor.	a. Thoracoscopy is automated. b. User uses haptic device to control introducer only.	a. Thoracoscopy is approximated. **b. Real surgical tools can be used.**
2	*Anatomical landmarks visualization and identification*	a. PE deformity observed. b. Patient-specific morphology c. Organs and anatomical landmarks observed.	a. PE deformity is reproduced by affecting sternum, associated costal cartilage and external skin of patient's avatar with a deformation model with a fall off **b. Simulated deformity is governed by parameters collected from CT data.** **c. 3D models of organs present including lungs, diaphragm, and beating heart textured via surgical photos obtained from operating room.**	a. PE deformity created with a physical spring attached to xiphoid process. b. Generic PE deformity is reproduced and is not patient-specific. c. Synthetic material is used to cast lung, diaphragm, and pericardium models. Primitive colors used, and heart is not beating.
		d. Deepest part of sternum. e. Intercostal spaces. f. Anterior axillary line (AAL) and mid axillary line (MAL).	Deepest point visualized. However, tactile determination of landmarks is absent and intercostal spaces not visible externally. AAL/MAL approximated.	**Exterior landmarks can be located by visualizing and feeling through synthetic skin on 3D-printed ribcage. AAL and MAL can be located.**
3	*Thoracoscopy*	a. Incision made for thoracoscope. b. Inspect PE deformation internally. c. Surgeon's assistant guides thoracoscope, focusing on tip of introducer.	a. Incision for thoracoscope is assumed to already exist. b. Virtual camera is available to visualize interior of virtual chest and internal intercostal muscle. c. Virtual camera follows introducer's tip at all times according to haptic device's motion. **A 30° angle is incorporated.**	**a. Incision can be made on replaceable synthetic skin.** **b. Web-cam is mounted on a long steel rod and can be inserted into chest.** **c. Assistant can maneuver web-cam.** A 30° angle is absent.

4	*Sternal elevation*	a. Make incision lateral to xiphoid process to make entry point of Rultract retractor rake. b. Using Rultract, crank up and elevate sternum gradually. c. Noticeable substantial relief of Pectus deformation is observed in thoracoscope.	a. Cutting and incision not implemented. b. Haptic interface limits implementing retractor. c. Sternal elevation is not implemented.	**a. Surgical scalpel can be used to perform step** **b. Actual surgical retractor can be used to perform step.** **c. Thoracoscopic view shows sternal lift.**
5	*Mediastinal tunneling*	a. Determine correct tunneling plane by applying small force brushing downwards on undersurface of sternum. Separation of tissue indicates safe spot. b. With aid of thoracoscope, guide introducer under sternum. c. Gently dissect mediastinum tissue with consideration of beating heart. d. When tunneling is achieved, puncture through exit site, examining externally. e. Pull tip of introducer out through established left incision site.	a. Pericardial sac can be seen beating in view, a thin layer can be identified between pericardial sac and sternum. b. Virtual camera follows tip of introducer. Targeted areas are viewed by aiming introducer towards them. **c.** User can pry along defined plane to dissect tissue and make pathway **while heart is beating.** d. Exit point is marked on interior of simulated left thorax, touching it will terminate simulation. e. Simulation ends when left side was reached.	a. Tunneling plane can be determined between synthetic pericardial sac and sternum. Tissue separation is observed. b. Maneuver camera to visualize targeted area. Synthetic organs in sight c. Brushing motion may be performed similar to surgery. Heart is not beating. **d. Puncturing can be performed through other side of synthetic muscle.** **e. Introducer tip can be pulled from left incision.**

Table 3. Required training aspects for a NPST and their current availability on a purely virtual (V) or a purely physical (P) setup.

Trainer Aspect	*Requirement*	*V/P?*
1. Visual / tactile cues	a. Observe external skin and feel intercostal spaces.	P
	b. Observe deformity externally and internally.	V
	c. PE deformity is interactive with user.	P
	d. Realistic and adjustable deformation of organs.	V
	e. Real-time dynamics: beating heart, blood emission.	V
2. Surgical tool mechanics	a. Realistic feeling of holding tool.	P
	b. Realistic pivot mechanics.	P
	c. Versatility of surgical tools.	P
3. Procedural tasks	a. Make markings on chest.	P
	b. Elevating sternum using surgical retractor.	P
	c. Mediastinal tunneling through substernal tissue.	P
4. User performance assessment	a. Track simulation lapse time.	V
	b. Track surgical tool economy of motion.	V
	c. Track type and number of errors made.	V
	d. Automated performance evaluation and calculation.	V
5. Patient-specificity	a. Models can be adjusted patient-specifically.	V
	a. PE is adjustable and can involve variability.	V
	b. Other complications can be integrated.	V
6. Usability / repeatability	a. Interface is intuitive and clear.	P
	b. Changeover between training sessions is minimum.	V

A hybrid simulator/trainer will, therefore, combine the components of the two previous modalities according to the allocation described in Table 3 and following the road map described by Obeid *et al*. in [26]. Some components were, however, implemented sub optimally in the previous two versions and other components have inherent flaws that should be addressed. The following is a summary of aspects from the previous two setups that require improvements when implemented in the hybrid setup:

- Issues and challenges: the following pre-existing issues should be addressed when implemented in the new hybrid system:
  - ⇒ Pivot mechanics: approximation of pivot behavior using the haptic device in the fully virtual simulator introduces an inherent discrepancy between the physical and the simulated pivot point because the haptic device's stylus doesn't support insertion. Since it will utilize the haptic interface, the hybrid setup must compensate for this discrepancy.
  - ⇒ Computationally expensive organ structures: the models of the organs in the virtual setup are composed of a single high-polygon mesh used for collision detection registered for rendering, deformation, and haptic interaction. This design is very expensive to process. A better structure must be incorporated.
  - ⇒ Slow soft-body deformation: implementation of soft-body deformation in the virtual setup uses a collision model generated from the original mesh of each organ and doesn't leverage the computer's Graphical Processing Unit (GPU), causing a dramatic loss in frames and hinders the performance. A more adequate high-performance design for deformations must be developed.
  - ⇒ PE deformity: in the virtual setup, the PE deformity affects the chest wall only. Tissues such as the mediastinum, pericardium, and diaphragm should also be affected by the deformity.
  - ⇒ Haptics: haptic forces are triggered using collision detection governed by the original high-polygon mesh rendered. Additionally, organ collision forces are based on a universal force type/property only. The hybrid setup

must optimize the haptic interface's collision detection and introduce organ-specific fore characteristics.

⇒ Unity engine: the virtual setup doesn't utilize the most recent version of the engine as it runs on version 4.6. The hybrid setup must utilize the potentials of the more recent releases of the engine.

- Additional requirements: after improving existing components from the previous two setups, several features that correspond to essential aspects of the surgery should be added to the hybrid NPST to ensure it provides the training skills required. These additions include:

⇒ The hybrid trainer must incorporate a platform to perform and train on lateral or subxiphoid sternal elevation, which is an essential step in the procedure.

⇒ The virtual setup doesn't include a facility to record and evaluate the user's performance. Such a component is needed.

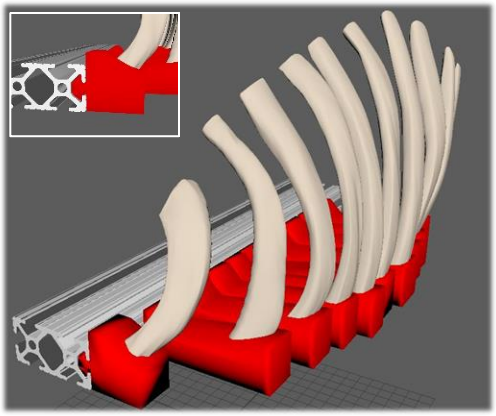
⇒ No complication scenarios are implemented where the user penetrates the pericardium and causes bleeding. Adding such a scenario expands the training scope.

5.2 Methods

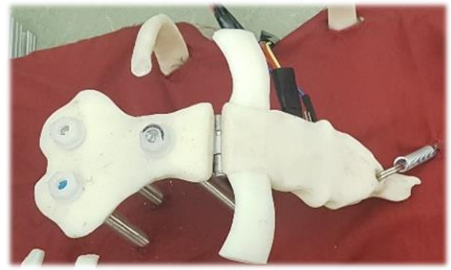
The previous section demonstrated how each simulator scheme has merits that the other cannot provide. A best-of-both approach is undertaken in this section to describe a design of a hybrid virtual/physical construction for the simulator. In a generic sense, the hybrid Nuss Procedure Surgical Trainer (NPST) integrates a physical semi-manikin of the thorax with a haptic-incorporated virtual environment.

5.2.1 Physical thorax

Seeing that the physical setup showed strong potential for implementing aspects that are relevant to the external visual and tactile cues of the simulator, a similar 3D-printed ribcage with synthetic skin and muscle will be adopted in the new approach. Since the physical constituent is employed to complement the virtual environment, only ribs of the right side of the chest (facing the user) as well as the sternum were 3D-printed and added to the thorax. The ribs and sternum were obtained from the modified Visible Human Project model [267, 268]. The ribs were mounted on an 80/20 [273] steel rail by complementing each rib with a modeled pin that fits the rail's openings (Fig. 39 (a)). The sternum articulates via an embedded metal hinge and is pulled down posteriorly via springs, along with the associated portion of the synthetic skin, to recreate a PE deformity (Fig. 39 (b)). This *training thorax* (Fig. 39 (c)) allows for marking the body, obtaining tactile cues from the skin, tool insertion, as well as the ability to use some of the original surgical tools and to perform trivial tasks such as marking relevant external landmarks, making incisions, and using the umbilical tape. Required surgical tools (scalpel, marker, Kelly clamp, etc.) were made available.



(a)



(b)

(c)

Fig. 39. Structure of the *training thorax* including (a) the modeled and 3D-printed ribs of the right of the ribcage and custom pins, (b) the 3D-printed sternum that articulates via an embedded hinge, as well as (c) the synthetic skin and muscle.

5.2.2 Thoracoscopy

The thoracoscopic view of the patient will convey from the virtual setup. To control the virtual thoracoscope, the user can choose between two modes: (1) the "auto-follow" mode where the camera constantly follows the tip of the introducer; and (2) the "controlled" mode where the user controls the thoracoscopic camera in real-time using a Wiimote. Since the hybrid setup utilizes a physical manikin, the Wiimote can be attached to a steel rod inserted in any intercostal space the surgeon decides. The Wiimote's pitch, roll and yaw motions control and update the rotation of the virtual thoracoscopic camera. The simulated virtual camera is equipped with a 30° angle as in the real surgery.

5.2.3 Patient specificity and PE deformity

Patient-specific modeling of the patient's PE deformity is reproduced as explained in Chapter 3. Parameters to describe the morphology can be obtained from CT data and converted into a single parameter (*depression*) that is inputted in to the simulation [260].

The system of morphed deformations with a parameterized falloff described in Chapter 3 is incorporated into the associated entities of the hybrid trainer's virtual environment. The envelopes of influence were, however, updated and supplemented using a system of *blend shape deformers* designed in Autodesk Maya [276] and incorporated as attributes for the torso, ribcage, internal intercostal muscle, diaphragm, pericardium, and mediastinum. Each organ affected by the PE deformity received a customized blend shape system that describes the gradient path of vertices' deflection upon some degree of deformation (Fig. 40). All affected organs are linked to a single global value of deformation in the simulation equal to the established *depression* parameter.

In the fully virtual simulator, the PE deformity was assigned at the start of the simulation and cannot be changed. In the hybrid NPST, however, the value of *depression index* was made a global variable and can change from 0 to 100; where 0 applies no degree of PE and 100 is the maximum depression. A module was incorporated to link the degree of PE deformity to the physical orientation of the sternum in the training thorax via *Arduino* communication. This module will be described in section 5.2.4.

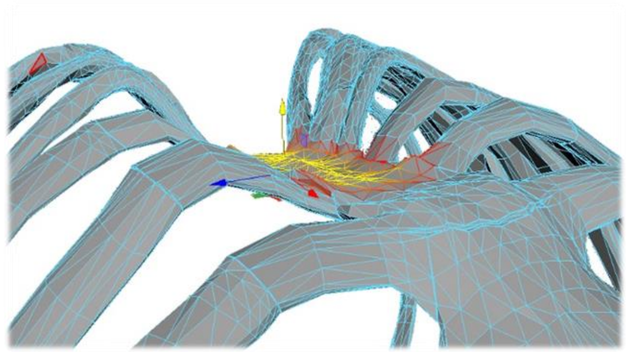


Fig. 40. Envelop of influence for deformation constructed to apply a cup-shaped morphology to the simulated ribcage.

5.2.4 Virtual/physical sternal elevation

A sensor was mounted on the undersurface of the 3D-printed sternum and connected to an *Arduino* platform to monitor its articulation and orientation at all times (Fig. 41). The sensor used is a 6-axis motion processing component that provides information in six degrees of freedom (3-axis gyroscope and, 3-axis accelerometer). For the purposes of the PE deformity, only the 3-axis accelerometer was utilized.

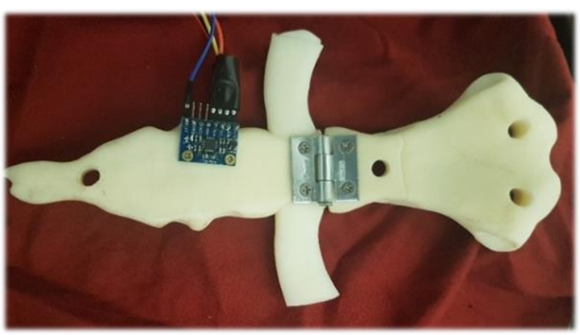
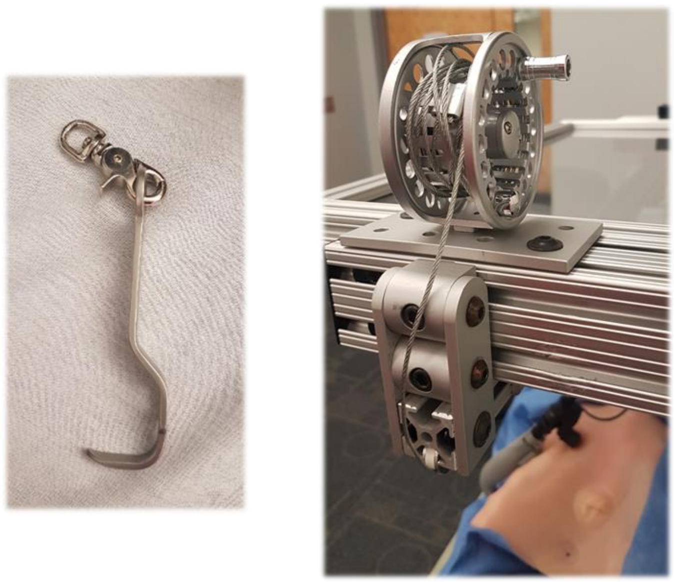


Fig. 41. Accelerometer installed on undersurface of sternum to monitor its articulation.

To incorporate the hybrid NPST with a facility to perform sternal elevation as deemed necessary by many experts, a cranking retractor mechanism was constructed and mounted on the apparatus above the training thorax. The device features a blunt tip Rultract® rake (Fig. 42 (a)) that can be inserted into the training thorax late and a cranking mechanism (Fig. 42 (b)) is used to elevate the sternum and hold it in place, using lateral or subxiphoid sternal elevation.



(a) (b)

Fig. 42. Cranking mechanism to train on sternal elevation.

5.2.5 Pivot Mechanics

As described before, the nature of generic (3-DOF) haptic device's end effector hinders an insertion behavior because the device's natural pivot, i.e., the stylus joint, physically travels with the user's motion; whereas, in reality, the tool's pivot is stationary at the insertion point. This discrepancy is, therefore, compensated for by augmenting the generic haptic device with an extension that implements a mechanism to utilize the device's natural pivot, while allowing the tool to be inserted into the training thorax appropriately.

After performing necessary measurements of the haptic device's stylus and associated components, this mechanism was designed, 3D-modeled, and prototyped using 3D printing (MakerBot Replicator Z18). The mechanism is composed of a component that controls and monitors the translational motion of the tool via *Arduino* communications (an open-source prototyping platform).

As the user attempts to move the tool through the insertion point (in the *z*-direction), a 3D printed component (Fig. 43) – not the stylus itself – slides through the extension affecting a 3D-printed wheel mounted to a rotary encoder connected to an Arduino Uno board. To simulate translational movements with respect to the fixed pivot, the tool's motion rotates the wheel affecting the rotary encoder. The rotation of the encoder is converted into translation of the surgical tool in the simulation.

This mechanism facilitates simulating an insertion behavior where the end effector is constrained from moving, while the user can maneuver through the extension utilizing the stylus' natural pivot, thus resolving the previously described discrepancy. This work was reported and validated by Obeid *et al*. [30].

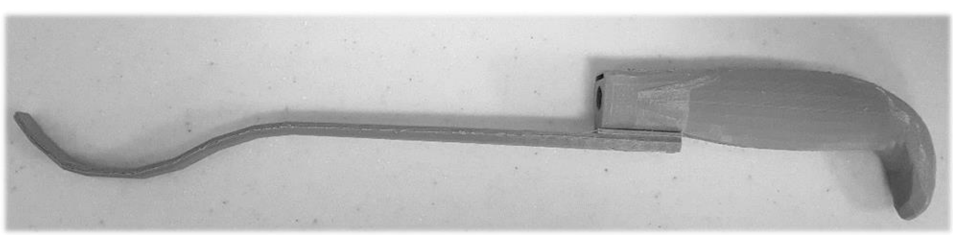


Fig. 43. 3D-printed handle that attaches to the haptic device's stylus and can be inserted into the training thorax.

5.2.6 GPU-leveraged soft body deformation

In the fully virtual setup, soft body deformation was based on collision models generated from the original mesh of each organ. Although soft body deformation upon colliding is achieved in this way, it is computationally expensive and causes a loss of many frames per second. Therefore, the hybrid NPST was incorporated with a facility to perform soft-body deformation in an efficient, optimized, and high-performance manner.

In order to increase the performance while producing realistic tissue and organ deformation, the GPU-leveraged unified particle-based simulation framework NVIDIA FleX [277, 278] was utilized to create a set of unified collision particles for each organ. The *Deformation model* of each organ, therefore, is composed of a cluster of such particles (spheres) of controlled size and count that are linked together with spring-based stiffness models (see Table 4 for example for the lungs). Collisions with these particles are solved as soft bodies described with appropriate stiffness parameters and deformation behavior models and, consequently, influence the *Render model* of the corresponding organ.

5.2.7 Recording performance

The hybrid NPST is a training platform. Such a platform is not complete without an automated way of collecting performance data to describe the user's behavior and convey scores that describe the adequacy of the performed tasks. Since the user's interaction with the internal organs are simulated, the virtual environment can be incorporated with a metric calculation and performance assessment facility.

The system infrastructure of the simulator was configured, and the various components were connected in a manner that allows for the collection of performance metrics. Automated real-time data acquisition regarding relevant metrics that describe the training session and the trainee's performance was constructed. The metrics that involve computing the number of organ collisions use a distinct collision system (the *Information model*) independent of that of the haptic, soft deformation, or render systems (see Table 4 for example for the lungs).

Through consultation with experts in Nuss procedure development and training, it was established that intraoperative cardiac perforation can be caused by using the tip of the introducer rather than its undersurface for mediastinal tunneling and/or applying too much pressure on the pericardium. Therefore, in addition to commonly recorded metrics such as completion time (sec) and total instrument path (mm), the performance-recording facility also calculates excessive instrument penetration time (total time introducer exceeds a given distance threshold from the center of the heart (sec)), total organ collisions (number of times the introducer's body collides with an organ (n)), as well as tip collisions (number of collisions between introducer's tip and the pericardium (n)). The value of each metric is updated in real-time during the simulation and is stored by the *Recorder*. The program generates a performance report associated with the trainee's log-in credentials at the end of the session.

5.2.8 Independent organ-specific haptic properties

Haptics implementation in the fully virtual version of the simulator utilized a universal set of properties for the force generated upon colliding with any organ indiscriminately. In order to incorporate a more realistic behavior, the dynamic link library (DLL) for Geomagic® OpenHaptics® Toolkit by [279] is integrated into the system to allow for organ-specific haptic force modeling. A set of parameters that describe the damping and stiffness of each organ were added to allow for an independent more specific behavior. Each organ's *Haptic model* (described in 5.2.9) is used to detect collision with the surgical tool and haptic force is generated accordingly. This collision system that communicates with the haptic interface is independent of that of the soft deformation, rendering, and performance recorder systems (see Table 4 for example for the lungs).

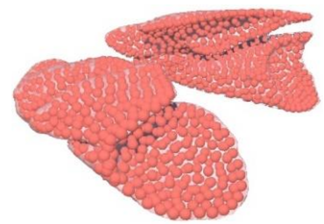
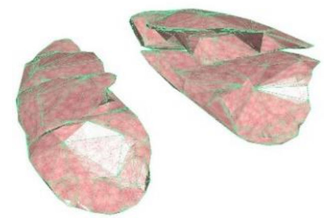
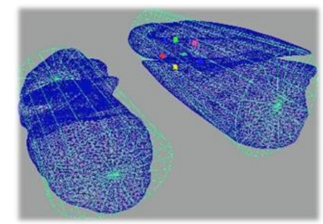
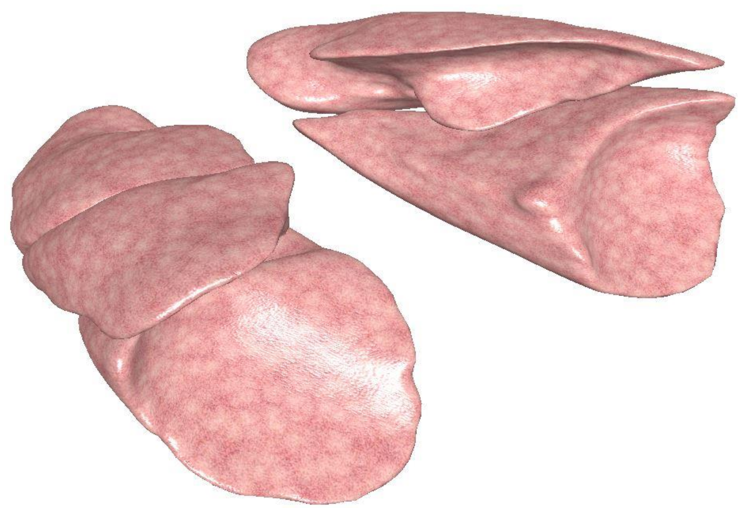
5.2.9 Optimized organ architecture

As described in sections 5.2.6 through 5.2.8, a multi-model architecture was constructed for each organ in the virtual environment. This sophisticated architecture ensures an independent processing of visual, deformation, and haptic interactions as well as an independent retrieval of information that describes the members involved in a collision.

Ultimately, the user only perceives the *Render model* which is the visual representation of the organ and its behavior. Internally, however, each organ is also composed of the *Deformation model*, the *Haptic model*, and the *Information model*. These models are used for collision detection but differ in type, function, granularity, and attributes. Table 4 provides a thorough description of all four models that make up the structure of each organ and how they interact with the environment.

Table 4. The four models incorporated into every organ in the scene. This architecture parallelizes the different functionalities and interactions for each organ.

		Render model	**Deformation model**	**Haptic model**	**Information Model**
Description		A high-resolution, high-polygon smooth mesh that describes the topography of the organ. High resolution texture and UV-maps were created and mapped according to this mesh.	A system made up of several clusters of identical particles (spheres) generated using NVIDIA Flex unified particles system to describe the volumetric shape of each organ. The particles are linked with spring-based stiffness models. Collision with particles affects their neighbors and drives a deformation of the "Render model". This system is processed on the GPU.	A low resolution coarse mesh, generated based on the original mesh of the organ but reduced using a feature-preserving vertices reduction algorithm. provides a superficial description of the organ's surface and interfaced with by the haptic device.	A trigger-based primitively shaped collider (sphere, capsule, cube) chosen appropriately for each organ. Physics-based interactions are not processed upon colliding with this mesh. Instead, information simply about whether or not a collision has occurred, and an identification of the colliding object is registered.
Attributes	*Rendered in the scene?*	**Yes**	No	No	No
	Drives organ deformation?	No	**Yes**	No	No
	Detected by haptics?	No	No	**Yes**	No
	Used by Recorder?	No	No	No	**Yes**
Function		This is the only mesh rendered to the viewer and is used to apply the surface texture of the organ.	Not rendered in the scene but detects collision between the surgical tool and members of the particle system. This system executes soft-body deformation of the organ based on the occurring collision.	Does not appear in the renderer but is nonetheless detectable by the haptic system. The mesh holds haptic properties that indicate how stiff the organ should feel (stiffness and damping).	Does not appear in the renderer and only sends a signal to the Recorder when a collision with it has occurred. Also sends the ID of the colliding object.

	Render model	**Deformation model**	**Haptic model**	**Information Model**
Example: Lungs				
Vertices count: Lungs	13,000 vertices	1,622 particles	367 vertices	84 vertices
Result: Lungs				

5.2.10 Dynamic interactions

The dynamics involved in the simulated surgery and virtual environment for the hybrid system will convey from the fully virtual setup. Physics-based interactions were modeled to deliver realistic behavior of the pericardium including a 2-stage motion for systole and diastole heartbeat. As the degree of PE deformity increases, according to the articulation of the sternum in the *training thorax*, the pericardium is squeezed and pushed laterally to the left and all adjacent entities of the body are deformed.

Through the developed multi-model architecture for simulating organs' behavior, collisions between the surgical tool and any organ causes soft-body deformations, generates corresponding haptic feedback, and is recorded as a collision event by the system.

A surgical complication is implemented where excess collision with and pressure applied to the pericardium causes cardiac perforation. If a consistent force applied to the pericardium exceeds a specified threshold, the haptic interface generates a release behavior where force feedback is immediately dropped to simulate puncturing. At that time, the surgical tool has exceeded a specified distance to the inner area of the pericardium which triggers an immediate blood emission and the simulation is terminated. The bleeding source is spawned at the puncturing location and the blood flow's direction and velocity are consistent with the surface normal. The fluid/blood particles are represented by 2D sprites and spheres and their trajectory is affected by a gravity field. Each particle increases in size once emitted by a predefined factor until it reaches the maximal size before being destroyed and disposed from the simulation after a specified limited amount of time.

5.3 Hybrid System Design Architecture and Components

As depicted in Fig. 44, the main constituents of the hybrid trainer are the *virtual environment module*, the *Arduino module*, the *hybrid pivot module*, and the *physical module*. Details pertaining to each of the modules are described in the following sections.

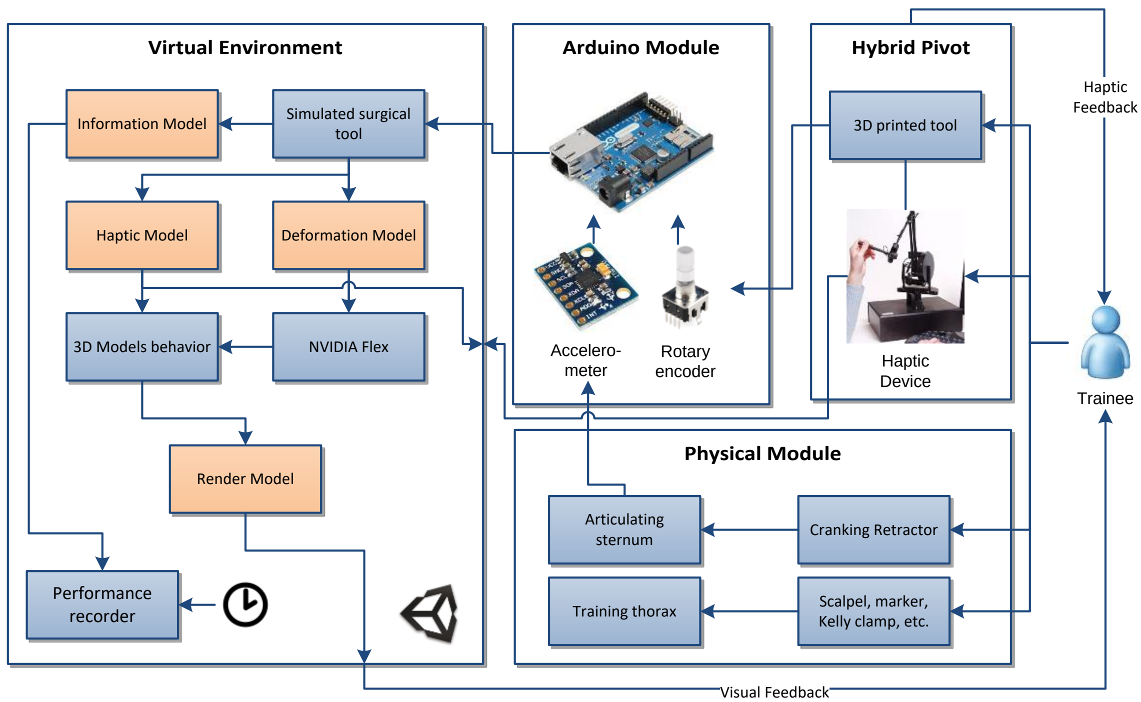


Fig. 44. Design architecture of hybrid Nuss procedure surgical trainer.

5.3.1 Physical module

The *Physical Module* of the trainer includes a training thorax (Fig. 39 (b)) that contains the right side of the ribcage, an articulating sternum, as well as synthetic skin and muscle. The user interacts with the physical module using surgical tools such as the scalpel, marker, or Kelly clamp (Fig. 32) as well as using the cranking retractor assembly that enables the user to perform lateral or subxiphoid sternal elevation. The user inserts the rake

(Fig. 42 (a)) into the training thorax lateral to the sternum and uses the cranking mechanism (Fig. 42 (b)) to elevate it and hold it in place. A synchronized immediate effect is observed in the virtual environment.

5.3.2 Arduino module

The *Arduino Module* includes a 3-axis accelerometer and a rotary encoder connected to an Arduino Uno board (Fig. 45). The accelerometer is mounted on the undersurface of the 3D-printed sternum and communicates real-time information that describe its articulation at all times (Fig. 41). The rotary encoder was installed in the *hybrid pivot* to control the insertion distance of the surgical tool.

A driver for this Arduino module was developed and incorporated in the Unity engine virtual environment to send and receive data. For this communication not to interfere with and affect the performance of the system, a multi-threading approach was used where the driver queries a separate CPU thread at each run to send information regarding the accelerometer's orientation and the encoder's rotation from the Arduino board to Unity.

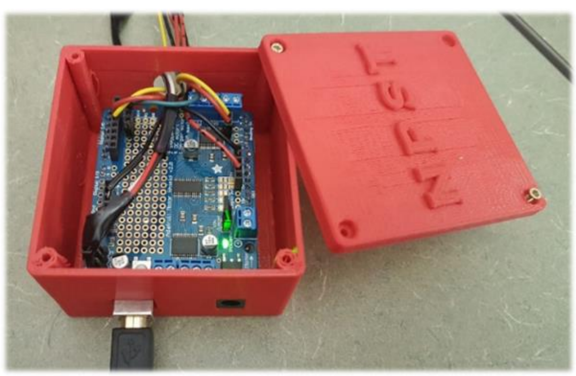


Fig. 45. Arduino Uno board as part of the Arduino module.

5.3.3 Hybrid pivot Module

The *Hybrid Pivot* is an integrated assembly that augments and attaches to the end-effector of the haptic device. The haptic device is relied on only for providing the surgical tool's orientation and rotation (yaw, pitch, and roll) during the simulation, whereas the *Arduino module* overrides the tool's translation in the *z*-direction via the rotary encoder. As the user inserts the 3D-printed handle that simulates the introducer (Fig. 43), a rotary encoder is affected moving the simulated surgical tool in the virtual environment.

5.3.4 Virtual environment module

Within the *Virtual Environment*, the models of the patient's torso, ribcage, the internal intercostal muscle, the diaphragm, as well as the pericardium and mediastinum tissue are all influenced, with flawless synchronization, by a system of morphed deformation of a parameterized falloff. The degree of PE deformation (simulated via the percentage of the *depression* parameter) is governed by the real-time orientation of the 3-axis accelerometer mounted on the physical sternum and connected through Arduino communication.

The interior of the simulated thorax contains the 3D models of the lungs, diaphragm, and the actively beating pericardium (Fig. 47 (c)). As the simulated surgical tool is inserted to perform mediastinal tunneling, it interacts with the multi-model system of organs to produce recorded collisions, soft-body deformations, and a haptic interaction.

The virtual environment was incorporated with a *Recorder* that performs automated calculation of elapsed simulation time, path tool length, number of organ collisions, and evaluates the extent to which the pericardium is penetrated.

A framework was implemented to detect puncturing of the pericardium and a system for blood emission is triggered when the introducer's penetration into the heart exceeds a specified threshold.

5.4 Results

The combination of virtual and physical components to form a hybrid setup capitalizes on the automatic, flexible, and controlled nature of a virtual reality system, coupled with the intuitive and perceivable nature of a physical manikin (Fig. 46). This section discusses the results regarding the trainer's interface, functionality, and performance.

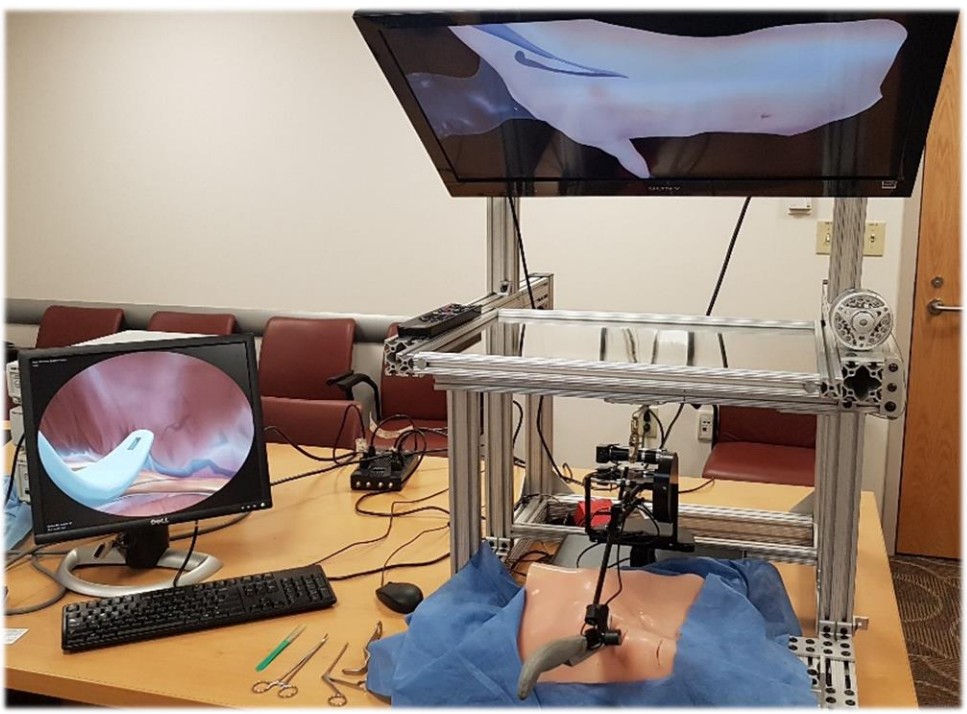
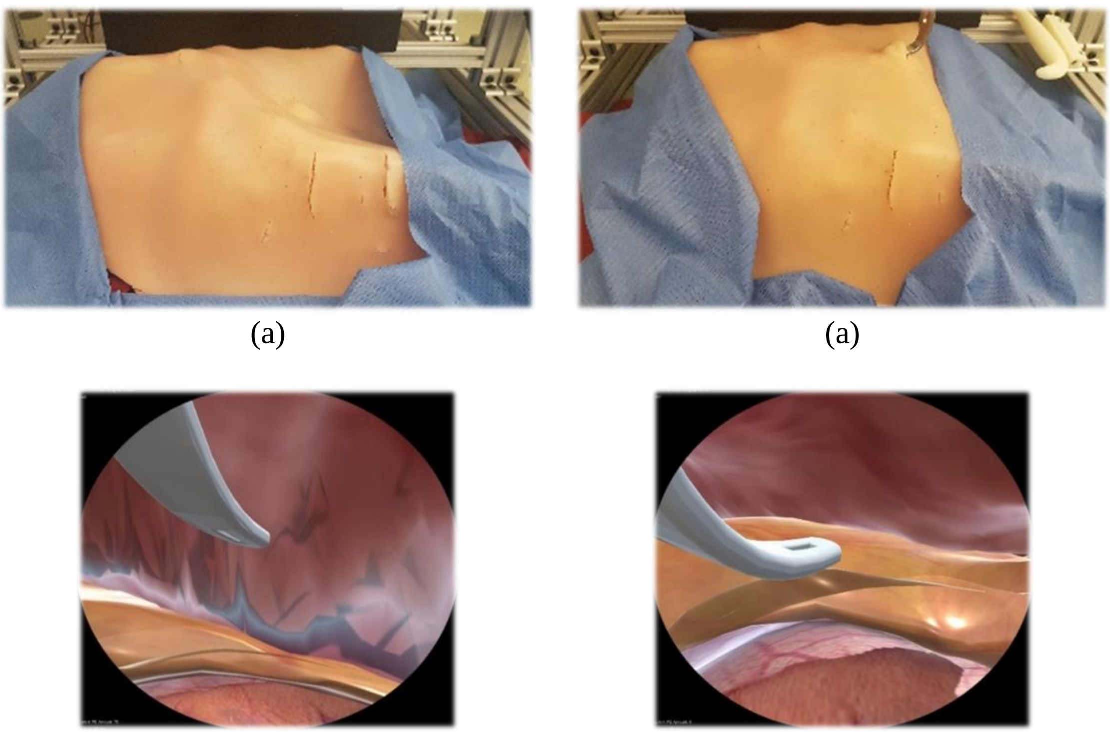


Fig. 46. The hybrid virtual/physical Nuss procedure surgical trainer (NPST).

5.4.1 Lateral or subxiphoid sternal elevation

The simulation starts with the trainee using a scalpel to make an incision at the appropriate place on the training thorax to insert the rake of the retractor under the xiphoid process to perform sternal elevation. As the trainee cranks the assembly and elevates the sternum, the simulated thoracoscopic view shows the model of the sternum moving correspondingly, thus relieving the formerly-depressed pericardium and making the path for mediastinal tunneling clearer (Fig. 47).



(a) (a)

(c) (d)

Fig. 47. Effect of using cranking retractor to elevate sternum. Moving sternum of physical training thorax affects directly and simultaneously the sternum and associated organs in the virtual environment: Training thorax showing degree of PE deformity (a) before and (b) after elevation. Thoracoscopic view of virtual environment showing degree of PE deformity (c) before and (d) after sternal elevation.

5.4.2 Thoracoscopy

Thoracoscopy can be guided with one of two modes: using a Wiimote to control the thoracoscope, or use an auto-follow mode where the camera automatically follows the tip of the instrument.

5.4.3 Mediastinal dissection

After properly elevating the sternum, the formerly depressed mediastinal area (Fig. 48 (a)) is relieved and the thoracoscopic view is immediately improved (Fig. 48 (b)). Following that step, the trainee inserts the 3D-printed surgical tool into the thorax and observes the simulated introducer moving in the thoracoscopic view (Fig. 48 (c)). The trainee then dissects the mediastinal tissue by carefully pawing down on the beating pericardial sac with the posterior surface of the introducer as it deforms posteriorly to this motion and the mediastinal tissue is observed to be dissected (Fig. 48 (d)). Fig. 48 (e) shows the mediastinal tunnel halfway created as both the mediastinal tissue and the pericardium deform posteriorly under the introducer as the introducer’s tip brushes against the undersurface of the sternum. At this stage, the trainee would feel the friction of the 3D-printed tool similarly brushing against the physical sternum in the training thorax. The mediastinal dissection process is continued (Fig. 48 (f-i) and a blue sphere comes into view on the internal intercostal muscle resembling the exit point. As the left side of the thorax is reached (Fig. 48 (j)), the simulation ends once the tip of the introducer reaches that exit site and the sphere’s color turns red (Fig. 48 (k)).

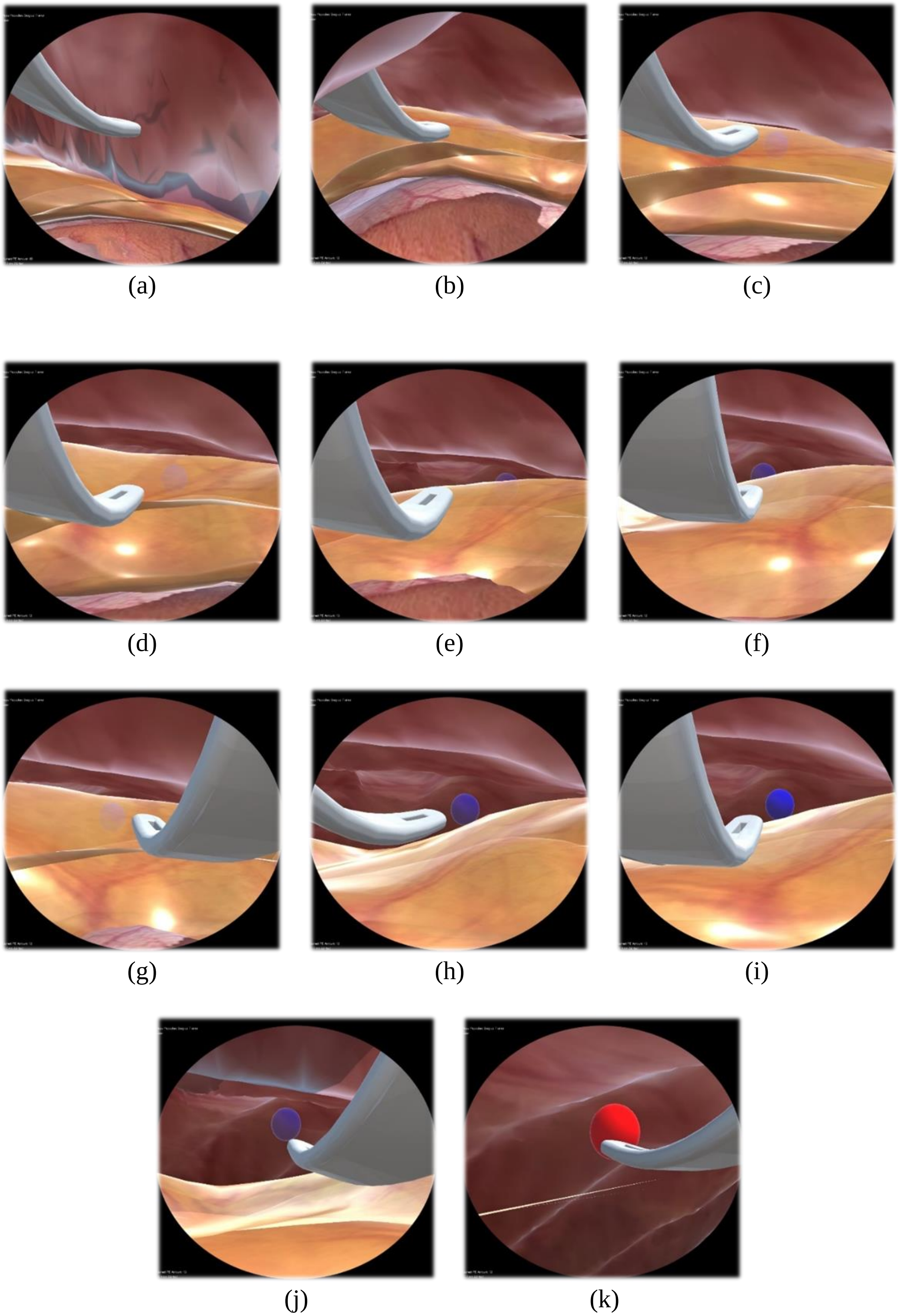


Fig. 48. Performing the mediastinal dissection on the hybrid NPST.

5.4.4 Soft-body deformation

During the simulation, soft-body deformation is observed upon colliding with the pericardium, the mediastinal tissue, the lung, or the diaphragm. These deformations are implemented as part of the multi-model architecture described in section 5.2.9 and their computations are executed on the GPU. Fig. 49 (a) and (b) show a soft-body deformation instance were the pericardium is deformed upon colliding with the tip of the introducer and Fig. 49 (c) and (d) show the underlying unified particle system for the deformation model.

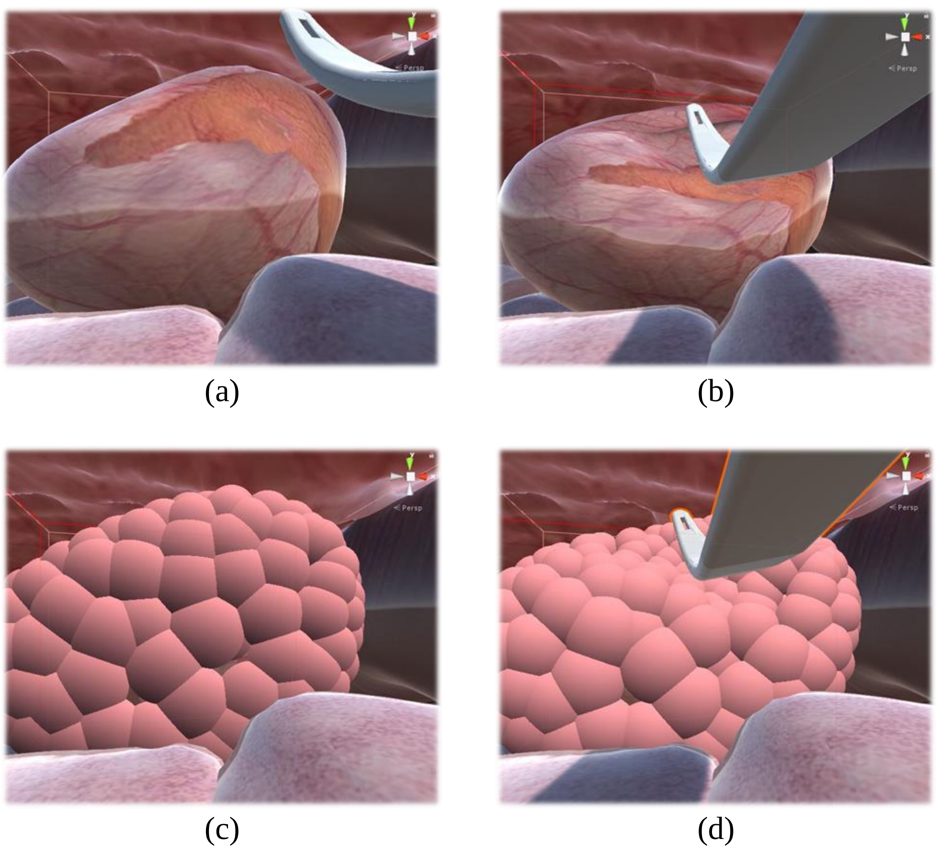
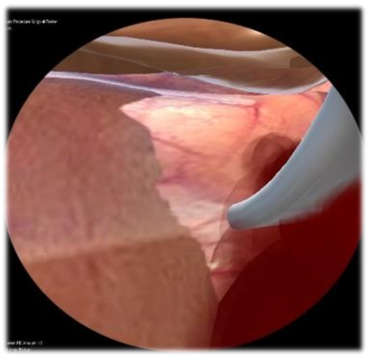
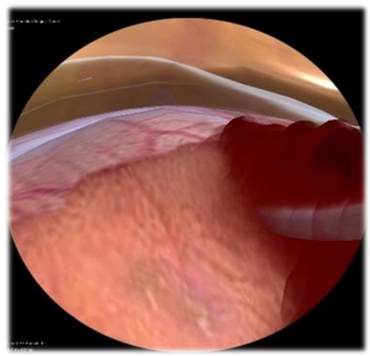


Fig. 49. Soft-body deformation of the pericardium: The Render model (a) before collision and (b) at collision. The same is demonstrated for the Deformation model in (c) and (d) showing the interaction with the underlying NVIDIA Flex particle system.

5.4.5 Complication: Cardiac perforation

At any point during the simulation, a complication scenario can be invoked if an incorrect plane is used for mediastinal dissection or if the introducer's tip is used instead of it undersurface. Upon applying an amount of pressure on the pericardium with the introducer's tip that exceeds the specified threshold, cardiac perforation takes place and blood is observed to flow from the penetration site (Fig. 50). The simulation will terminate if that event occurs.


(a)


(b)

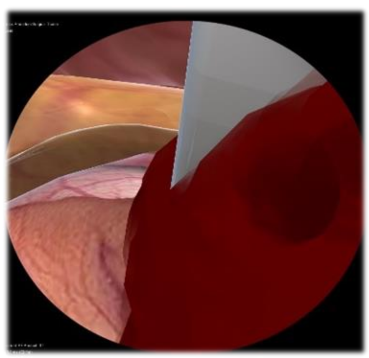

(c)

Fig. 50. Complication scenario during mediastinal dissection: Cardiac perforation and bleeding. (a) force applied using the tip of the introducer has exceeded the predefined threshold and the pericardial tissue has been penetrated, (b) blood flow increases, and (c) view is obscured by blood and simulation terminates.

5.4.6 Delegation of training requirements to system components

The hybrid Nuss procedure surgical trainer (NPST), allows for realistic tactile assessment of the physical torso and the use of actual surgical tools to provide adequate training on the sternal elevation and the mediastinal tunneling skills. The integrated Recorder measures and monitors the motion of the surgical tool and reports relevant user performance metrics. Table 5 shows the delegation of each of the NPST requirements discussed in section 5.1 to the various constituents of the developed system along the virtual-physical continuum.

Table 5. Delegation of each training requirement to components of the hybrid Nuss procedure surgical trainer (NPST) as they relate to the virtual/physical continuum.

Virtual ⟷ **Physical**

	Virtual Environment Module			**Arduino Module**		**Hybrid Pivot Module**			**Physical Module**		
Trainer requirement #	*Collision/ rendering*	*NVIDIA FleX*	*Perf. Recorder*	*Accelero-meter*	*Rotary encoder*	*Haptic device*	*Hybrid pivot*	*3D-printed extension*	*Training thorax*	*Surgical tools*	*Cranking retractor*
1a. Ext skin + ribs									X		
1b. PE ext. & int.	X								X		
1c. Interactive PE	X			X					X		
1d. Def. organs	X	X									
1e. Heartbeat & bleed	X										
2a. Realistic tool								X			
2b. Realistic pivot							X				
2c. Versatile tools										X	
3a. Make markings									X		
3b. Sternal elevation				X					X		X
3c. Med tunneling	X	X			X	X	X	X			
4a. Track lapse time			X								
4a. Track tool path			X			X					
4a. Track # collisions			X			X					
4a. Generate metrics			X								
5a. Patient-specific	X										
5b. Adjustable PE	X			X							
5c. Complications	X										

5.4.7 In-vitro validation of the Recorder

An in-vitro validation experiment was conducted to verify the functionality of the performance-recording system when a particular behavior is intended. Three scenarios were executed (10 runs each) and average performance metrics are reported in Table 6:

- Scenario 1 – *minimizing errors*: collision with any organ but the pericardial sac was avoided, excessive pressure on pericardial sac was avoided, and the undersurface of the instrument (not its tip) was used for mediastinal tunneling.
- Scenario 2 – *excessive penetration*: intentional excessive penetration was applied to the pericardial sac and the instrument's undersurface was used for tunneling.
- Scenario 3 – *tool tip perforation*: mediastinal tunneling was intentionally performed using the tip of the introducer not its undersurface.

Results show that the simulator can faithfully reflect the intended behavior in each scenario. Lower count of total organ collisions and excessive instrument penetration was observed in Scenario 1, longer excessive penetration was observed in scenario 2, and higher count of tip collisions and excessive penetration was observed in scenario 3.

Table 6. Reported performance metrics for three validation scenarios.

Performance Measure	**Scenario # (n = 10)**		
	1	*2*	*3*
Avg. completion time (sec)	87.1	106.3	98.3
Avg. instrument path (mm)	171.1	159.8	222.9
Avg. organ collisions count (n)	1.2	1.9	5.6
Avg. excessive penetration (sec)	0.9	19.1	19.4
Avg. tip collisions count (n)	0.7	9.1	33.4

CHAPTER IV

VALIDATION

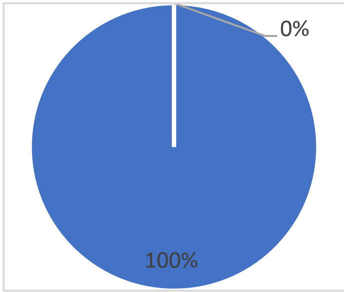
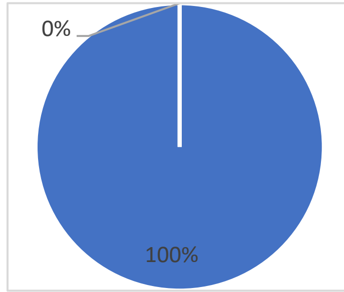
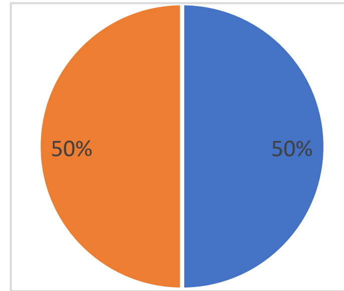
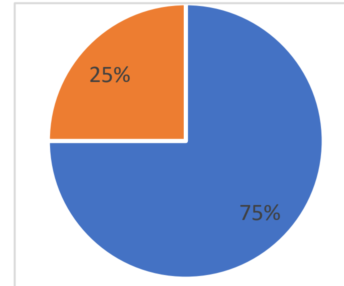
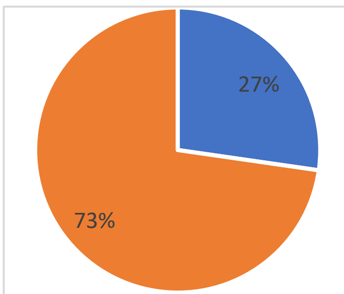
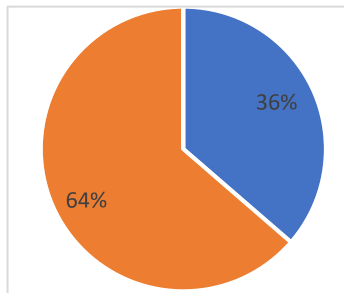
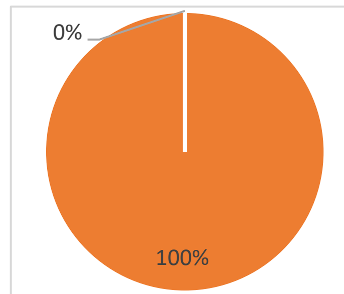
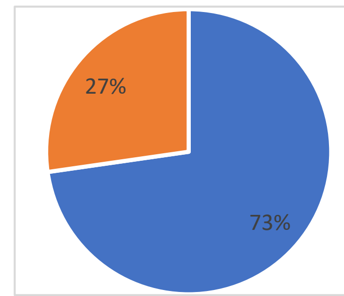
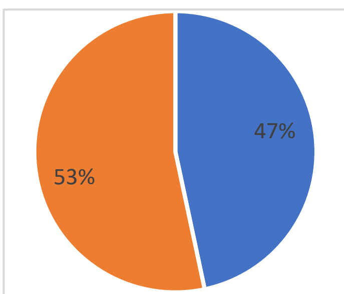
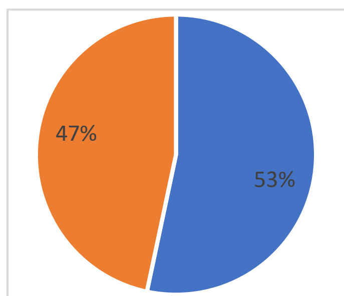
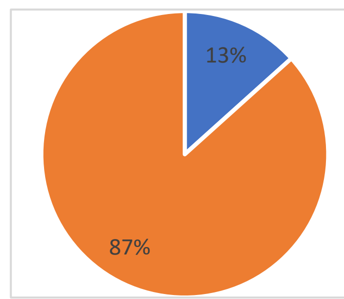
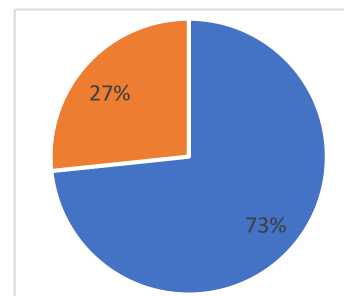
Rigorous evaluation, assessment, and validation is essential following the development of a new simulation and training system to establish its utility and faithfulness. The fifth aim of this dissertation is to demonstrate the validity of the developed hybrid trainer. This chapter details the design and obtained outcomes of experiments performed to establish primary validation entities including face, content, and construct validities.

6.1 Study Design and Demographics

A user study was designed to deploy the Hybrid NPST at the Children's Hospital of the King's Daughters (CHKD) and invite two cohorts of medical professionals to participate. The main objective is to obtain necessary subjective and objective evaluation of the system to establish its validity as a training instrument. The Old Dominion University Institutional Review Board (IRB) approved the study (IRB #: 1077126-2).

A total of 15 subjects (9 males and 6 females) participated in this study. The participants included two groups: 4 experienced surgeons (experts) and 11 residents/students (novices). The age ranged from 40 to >50 for experts and from 20 to 40 for novices. Surgical experience ranged from 12 to 33 years (23 ± 9) for experts and from 0 to 9 (2.3 ± 2.7) for novices. Table 7 shows details about the participants' demographical information displayed in the form of pie charts. It is worth pointing out that all experts have previously performed the NP and none of the novices received simulation-based training for the NP.

Table 7. Demographics of participants in the user study.

	Performed NP?	Received NP Training?	Received Simulation-based Training on NP?	Used Simulators?
Experts				
Novices				
All				

■ YES , ■ NO

6.2 Protocol of the Study

All participants were asked to complete a short pre-questionnaire before using the system to provide information about prior surgical experience as well as experience with surgical trainers and simulators.

All participants were then asked to complete three training trials on the hybrid NPST. In each trial, the participant performed sternal elevation using the cranking mechanism as well as performed mediastinal dissection (tunneling) by passing the simulated surgical tool from the right side to the left side of the simulated thorax, while observing and monitoring the process in the simulated thoracoscopic view. Each participant received an instructional briefing about the simulation with aid of a video of the real surgery. The simulation terminates automatically upon reaching the specified location on the left side of the thorax.

After completing the 3 simulation trials, each participant was asked to complete two post-questionnaires. The post-questionnaires provided the user's evaluation of the fidelity, as well as the training capacity of the hybrid NPST, respectively.

6.3 Face Validity

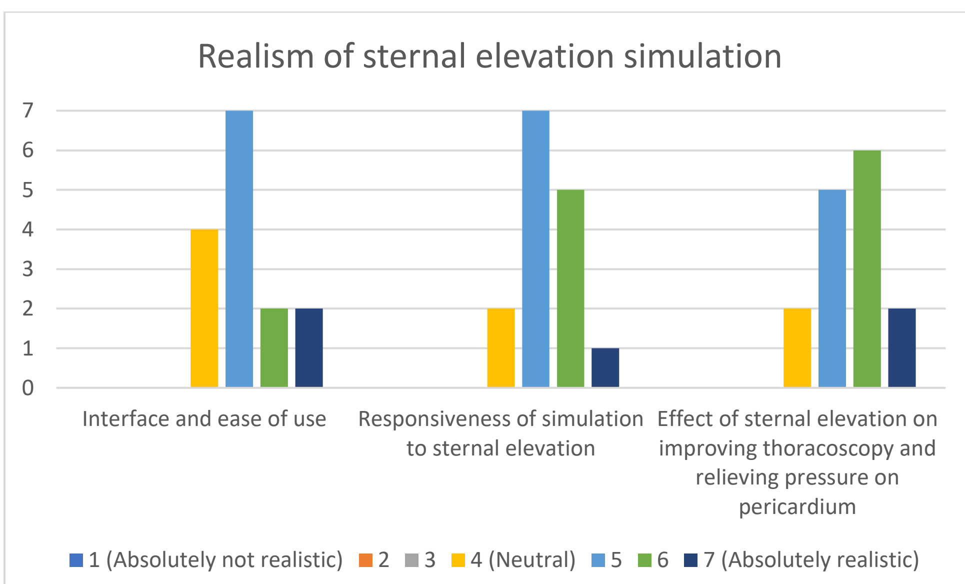
Face validity evaluates the extent to which the simulator resembles the real system as judged by users. After using the simulator, the participants were asked to subjectively evaluate the simulator's esthetics, realism, and fidelity with special focus on four aspects relating to the surgery: realism of using the cranking mechanism for sternal elevation, realism of organ simulation and visualization, realism of the mediastinal dissection process, and overall realism.

6.3.1 Methods

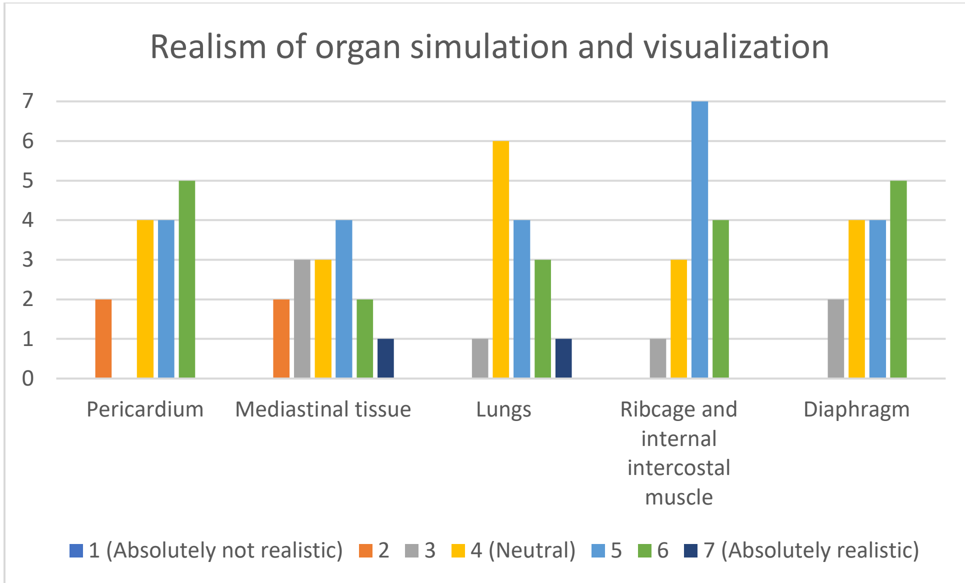
A 1–7 Likert scale was employed in this experiment, with 1 being *Absolutely not realistic* and 7 being *Absolutely realistic*. The participants were also able to leave anonymous feedback regarding the system's realism for future and further improvement. The instrument (questionnaire) used is included in Appendix A.

6.3.2 Results

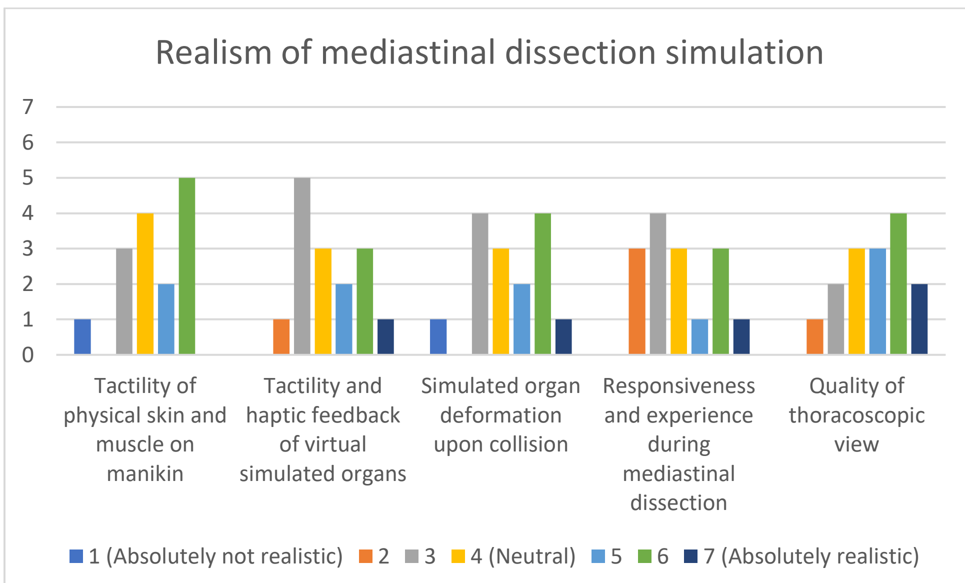
The complete evaluation of the various aspects of realism for the hybrid NPST is displayed in Fig. 51. For the Overall Realism category (Fig. 51 (d)), 67% of the participants judged the *first impression* and the *user design* as ''5 – somewhat realistic, 6 – realistic, or 7 – absolutely realistic''. This score (5 or higher) was given by 27%, 47%, and 60% of the participants for the *introducer manipulation*, the *synchronization between virtual and physical components*, and the *overall realism*, respectively.



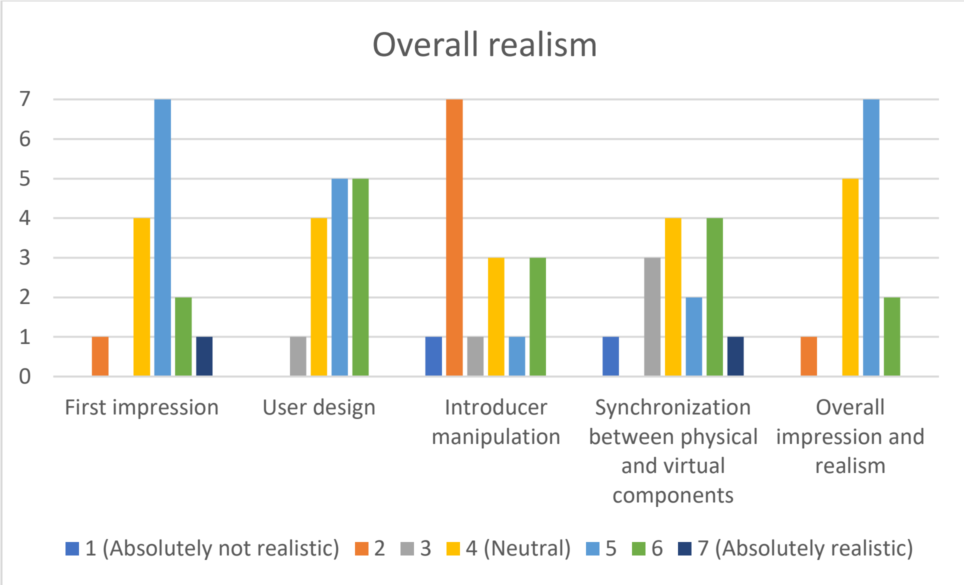
(a)


Realism of organ simulation and visualization
7
6
5
4
3
2
1
0
Pericardium
Mediastinal tissue
Lungs
Ribcage and internal intercostal muscle
Diaphragm
1 (Absolutely not realistic)
2
3
4 (Neutral)
5
6
7 (Absolutely realistic)

(b)


Realism of mediastinal dissection simulation
7
6
5
4
3
2
1
0
Tactility of physical skin and muscle on manikin
Tactility and haptic feedback of virtual simulated organs
Simulated organ deformation upon collision
Responsiveness and experience during mediastinal dissection
Quality of thoracoscopic view
1 (Absolutely not realistic)
2
3
4 (Neutral)
5
6
7 (Absolutely realistic)

(c)



(d)

Fig. 51. User evaluation of the NPST's realism with respect to: (a) using the cranking mechanism for sternal elevation, (b) organ simulation and visualization, (c) mediastinal dissection process, and (d) overall realism.

6.4 Content Validity

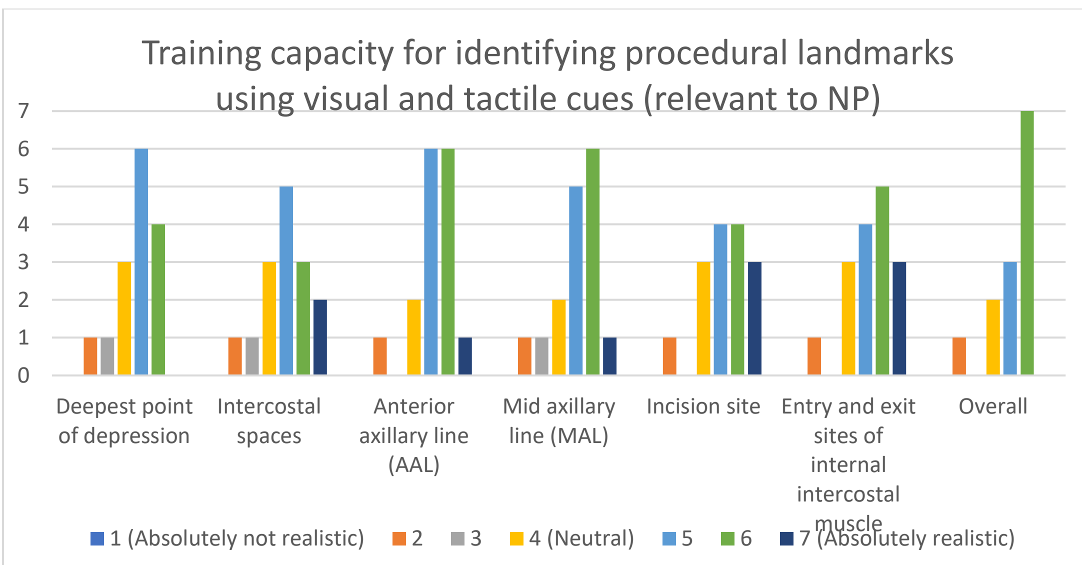
After using the simulator, the participants were asked to subjectively evaluate the simulator's capacity and appropriateness for training on the Nuss procedure with special focus on four aspects relating to the surgery: Training capacity for identifying procedural landmarks using visual and tactile cues, training capacity for sternal elevation, training capacity for mediastinal dissection, and overall training capacity.

6.4.1 Methods

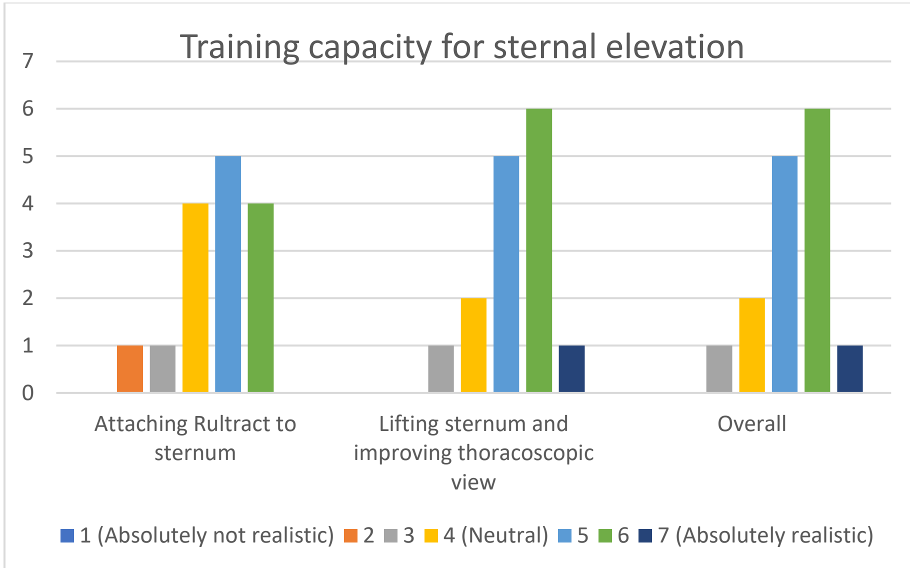
A similar 1–7 Likert scale was employed in this experiment, with 1 being *Absolutely not useful* and 7 being *Absolutely useful*. The participants were also able to leave anonymous feedback for suggested improvement to aspects relating to positive training. The instrument (questionnaire) used is included in Appendix A.

6.4.2 Results

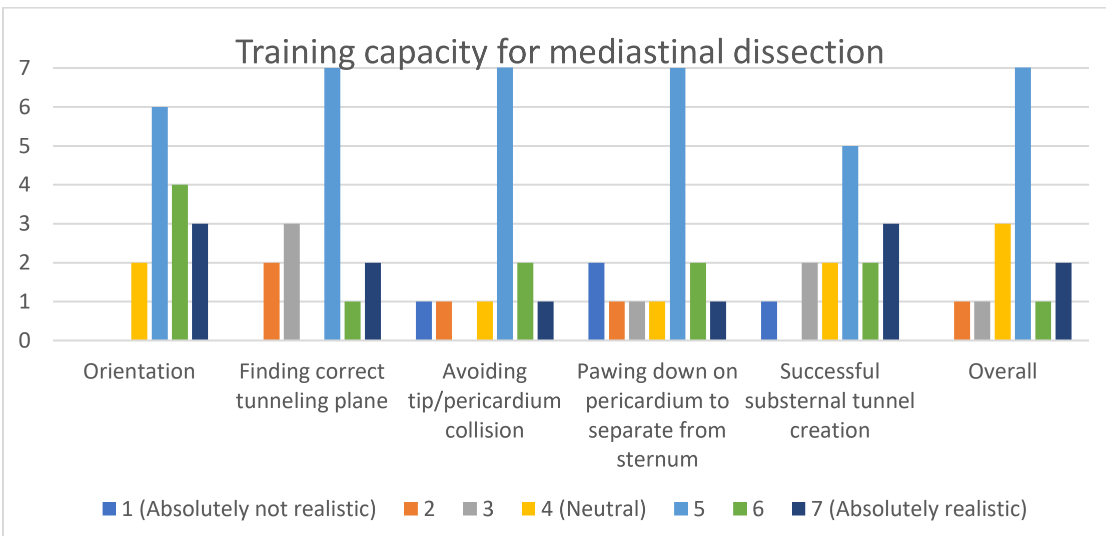
The complete evaluation of the various aspects of training capacity of the hybrid NPST is displayed in Fig. 52. For the Overall Training Capacity category (Fig. 52 (d)), the percentage of participants that gave a score of ‘‘5 – somewhat useful, 6 – useful, or 7 – absolutely useful” were as follows: 73% for training capacity of *introducer manipulation*, 80% for training capacity of *hand-eye coordination*, 87% for training capacity of *special properties of the Nuss procedure*, and 73% for *overall training capacity*.



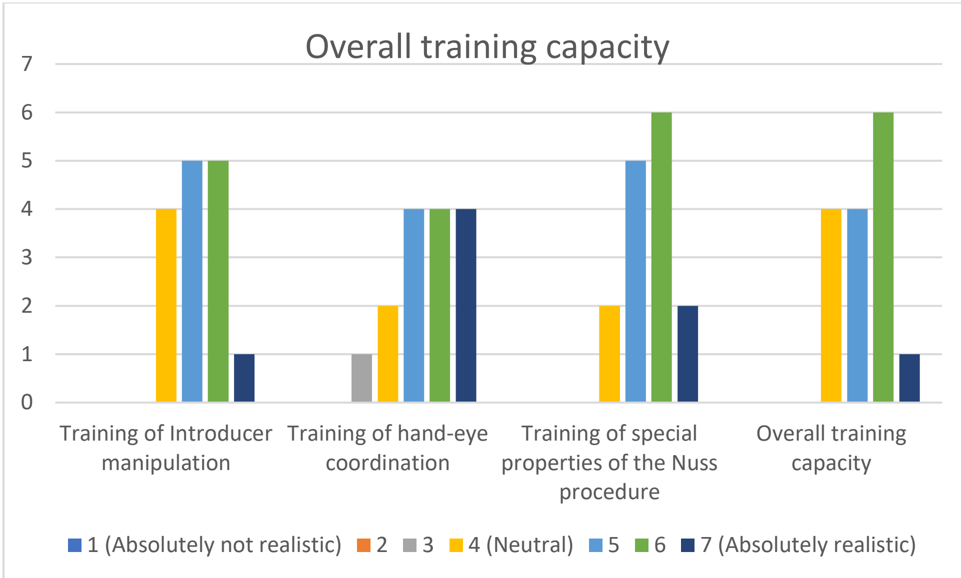
(a)


Training capacity for sternal elevation
7
6
5
4
3
2
1
0
Attaching Rultract to sternum
Lifting sternum and improving thoracoscopic view
Overall
1 (Absolutely not realistic)
2
3
4 (Neutral)
5
6
7 (Absolutely realistic)

(b)


Training capacity for mediastinal dissection
7
6
5
4
3
2
1
0
Orientation
Finding correct tunneling plane
Avoiding tip/pericardium collision
Pawing down on pericardium to separate from sternum
Successful substernal tunnel creation
Overall
1 (Absolutely not realistic)
2
3
4 (Neutral)
5
6
7 (Absolutely realistic)

(c)



(d)

Fig. 52. User evaluation of the NPST's training capacity with respect to: (a) identifying procedural landmarks using visual and tactile cues, sternal elevation, mediastinal dissection, and overall training capacity.

6.5 Construct Validity

In this section, the trainer's ability to detect quantitative differences in performance between various levels of surgical expertise was investigated. The system's ability to provide a statistically significant discrimination between the two levels of expertise establishes its construct validity signifying its ability to measure performance and viability as a training platform.

6.5.1 Methods

An experiment was carried out to investigate the NPST's ability to distinguish the experienced from the novice participants. A Recorder facility was incorporated into the system to automatically collect information pertaining to the following objective performance metrics:

1. Completion time in seconds.
2. Total instrument path in millimeters.
3. Excessive instrument penetration (total time the introducer exceeds a given distance threshold from the center of the hear) in seconds.
4. Total number of instrument-body collisions with organs.
5. Total number of instrument-body collisions with the pericardium
6. Total number of instrument-tip collisions with the pericardium.

All participants received instructions on how to perform the procedure and were shown an instructional video for sternal elevation using a Rultract® as well as for the mediastinal dissection process. Participants then completed three consecutive trials on the NPST system and received brief feedback between trials. The objective of the simulation run was to perform mediastinal dissection while minimizing collisions with organs and pressure applied to the pericardium.

It is hypothesized that the group of experienced surgeons will outperform the group of novices in metrics that quantify the user's skill in performing mediastinal dissection with minimized errors. Comparisons of mean performance measures for each metric between the two groups were made using a Mann-Whitney U test.

6.5.2 Results

The experts group displayed better performance than the novices group for skills relevant to correct mediastinal dissection. This was demonstrated by the shorter excessive penetration time: 7.5 ± 8.8 for experts versus 20.5 ± 10.7 for novices with statistically significant difference ($p < 0.05$) (Fig. 53 (c)); as well as fewer tip-heart collisions: 6 ± 3.81 for experts versus 16.3 ± 12 for novices with statistically significant difference ($p < 0.05$) (Fig. 53 (e)). There was no statistically significant difference between the two groups for simulation time, total tool path, and body-organ collision metrics (Table 8).

Table 8. Statistical test results for performance metrics.

Metric	**Experts**	**Novices**	**p-value** [a]
Time (sec)	130.2 (60.4)	86.2 (40.8)	0.053
Total Tool Path (mm)	110.1 (69.1)	144.1 (79.4)	0.118
Excessive pen time (sec)	7.5 (8.8)	20.5 (10.7)	**0.002**
Body-organ collisions (n)	2.11 (1.8)	13.4 (17.5)	0.160
Body-heart collisions (n)	23.33 (17.36)	21.56 (17.52)	0.781
Tip-heart collisions (n)	6 (3.81)	16.3 (12.0)	**0.006**

[a] ***Mann-Whitney U test***

These results showed that the simulator was able to reflect a difference in expertise level between experts and novices for mediastinal dissection with respect to pressure applied on the heart as well as avoiding using the tip of the surgical tool for dissection. This demonstrates preliminary construct validity of the mediastinal dissection task on the hybrid NPST.

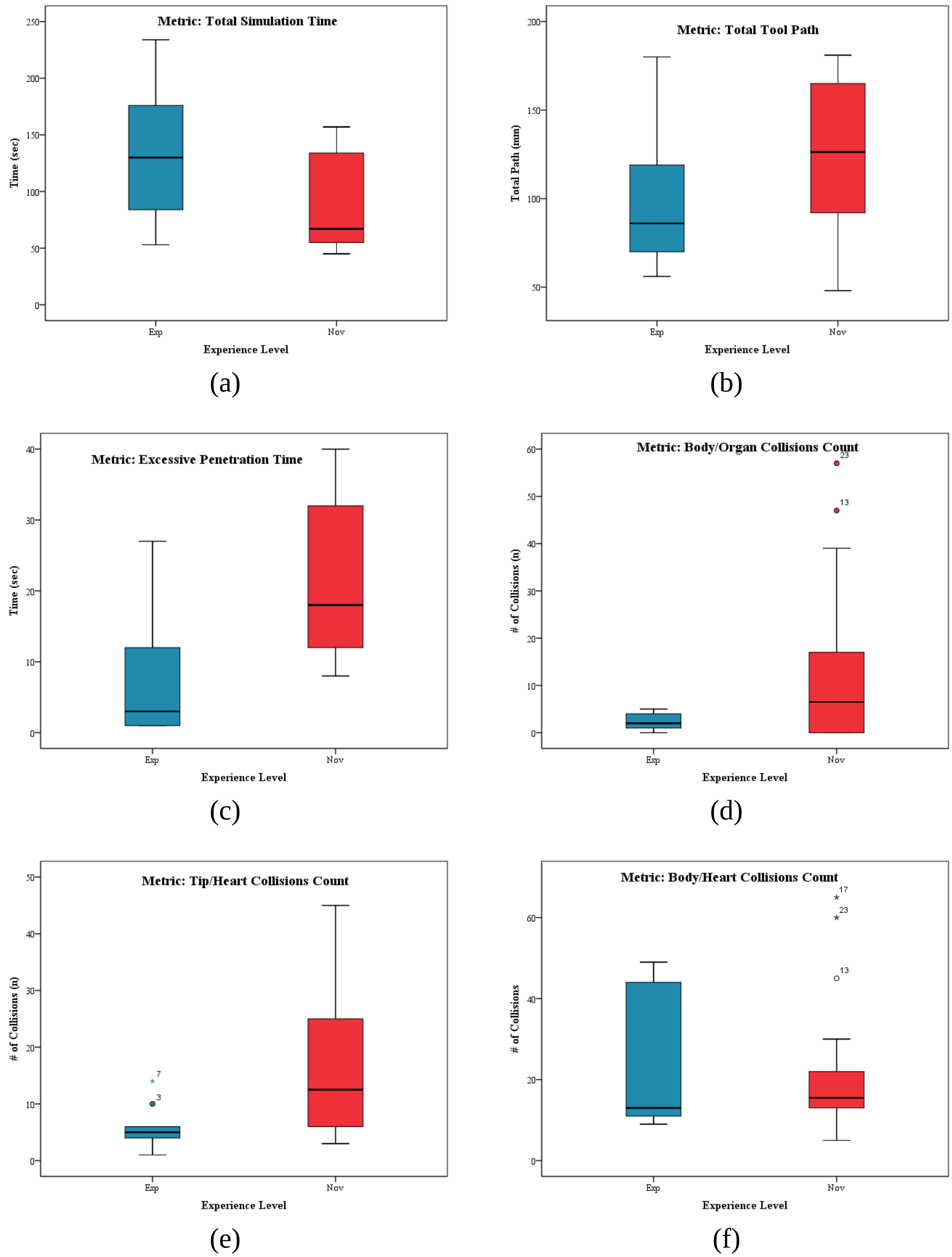


Fig. 53. Performance difference between experts group and novices group for various metrics: (a) simulation time, (b) tool path, (c) excessive penetration time, (d) tip-heart collisions, (e) body-organ collisions, and (f) body-heart collisions.

CHAPTER VII

CONCLUSIONS AND FUTURE WORK

This dissertation discussed the development, design, and utility of a surgical training platform for the Nuss procedure – the minimally invasive technique to correct the congenital chest wall deformity pectus excavatum (PE). The development involved an exploration of virtual reality- as well as physical-based surgical simulation modalities to exploit their limitations and identify aspects where each adds value. The resulting system is a hybrid mixed-reality trainer.

7.1 Virtual Simulator

A fully virtual simulator for the procedure was constructed by integrating a patient-specific virtual environment with a haptic interface. In this setup, the user manipulates the surgical instrument using a haptic device and interacts with an avatar of the patient and relevant organs. A simulated thoracoscopic view displays the instrument's behavior within the thorax. A patient-specific model for the PE deformity was developed to allow for tailoring the avatar to parameters obtained from CT data. The anatomically-correct environment was constructed using footage from real surgery combined with 3D modeling techniques.

7.2 Physical Simulator

A fully physical manikin-based platform for simulating the procedure was also constructed to explore the other extreme of the virtual-physical spectrum where a PE-deformed ribcage was designed, 3D-printed, and coupled with synthetic materials for the skin, muscle, and organs. The sternum was pulled posteriorly using springs and fixed in place; and the real surgical tools were made available for training.

7.3 Evaluating the Two Simulators

Realistic simulation of an entire surgical procedure is not a feasible goal with current technology. A more dominantly practical approach is to follow a task breakdown procedure of the surgery to identify the most relevant aspects to be included in the simulation. Therefore, this work performed this task breakdown for the Nuss procedure and, based on experts' opinion, identified the significance of each task.

This dissertation then compared the two simulation platforms constructed against the conducted task breakdown of the surgery resulting with an identification of the areas where each setup contributes more and identified the limitations of each.

A fully virtual environment enables automated user assessment and patient-specificity. The virtual and flexible nature of the simulation allows for adjusting the models and morphologies to patient-specific data, provides a wider training scope through the ability to introduce surgical scenarios and complications, as well as involves a higher fidelity simulation through incorporating dynamic visualizations such as breathing and heart beating. Such an environment, however, has limited ability to reproduce a surgical tool’s mechanics as it relies on a haptic interface for the approximation of physical constraints. It is also infeasible in such an environment to simulate procedures that require the usage of several surgical tools and retractors.

On the other hand, the fully physical variety of the simulator suffers no issues in aspects relating to tool mechanics as well as visual and tactile cues. Its training scope, however, is very narrow because of the involved changeover between uses and the difficulty in incorporating patient-specific components and dynamic interactions.

7.4 The Hybrid

A hybrid virtual-physical simulator and trainer was developed utilizing the successful components of the two previous versions. This capitalizes on the merits of having a physical external manikin that allows for realistic tactile assessment of the torso and the use of actual surgical tools, coupled with the power of a virtual environment that integrates an interactive and realistic patient-specific model of the patient's torso and deformity with the ability to generate accurate haptic force feedback and automatically measure the user’s performance.

Through the development of the NPST, three main challenges were addressed: (a) the ability to reproduce an interaction between the user and the environment through visual and tactile cues, addressed through incorporating appropriately placed sensors and synchronizing virtual and physical coordinate spaces; (b) the compensation for a discrepancy between virtual and natural pivots when utilizing a haptic interface for tool insertion, addressed by constructing an augmentation for generic haptic devices to account for said discrepancy; and (c) the requirement to process high fidelity visualization, soft-body deformations, and haptic interactions for anatomically-correct organs while preserving and recording collision events and information for user performance evaluation, addressed by developing a multi-model architecture that describes and implements the behavior of each organ in a parallel manner.

7.5 Validation Study

A user study was conducted to establish face, content, and construct validity of the system. According to the respondents, the hybrid NPST provides a realistic reproduction of important aspects of the Nuss procedure (60% of participants judged it as realistic) and is an adequate platform for training (73% of participants judged that it has capacity for useful training). Additionally, the trainer was able to distinguish between various levels of expertise with regards to metrics that measure the surgeon's correct and safe mediastinal dissection.

7.6 Future Work

The hybrid NPST delivers a platform for simulating the surgery. It focuses, however, on specific surgical tasks relevant for sternal elevation and mediastinal dissection. Future work can address the reproduction of other aspects of the surgery such as: subcutaneous tunneling, left lung simulation and interaction, as well as bar placement and securement.

Furthermore, the developed architecture for simulating organs with associated interactions could benefit greatly from further experimentation with a different procedure that involves different organs. This could further demonstrate the utility of the architecture and generalize its purpose.

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APPENDICES

APPENDIX A: VALIDATION STUDY INSTRUMENTS

The instruments (questionnaire's) used to obtain the necessary information for the user study (IRB #: 1077126-2) are shown here:

Pre-questionnaire

Participants were asked to complete the following questionnaire before using the NPST system. It provides demographical information and a description of surgical experience:

1. Age range? (20 – 30, 30 – 40, 40 – 50, or >50)
2. Role at medical institution?
3. Are you a resident? If yes, what year/specialty? If no, how long is your post-residency experience (years)?
4. Surgical experience (number of years)?
5. Have you performed the Nuss procedure? If No, please proceed to question 8.
6. How long is your experience with the Nuss procedure (number of years)?
7. How many Nuss procedures do you do yearly?
8. Have you received any training on the Nuss procedure?
9. Have you received simulation-based training on the Nuss procedure?
10. Do you have prior experience with surgical trainers?

Post-questionnaires

Participants were asked to complete the following two-part questionnaire after using the NPST system. It provides an evaluation of the user's experience with the system after trying it as well as an evaluation of the system in a training capacity.

PART I: Please evaluate the **realism** of the NPST system and its components. (1-absolutely not realistic, 4-neutral, 7-absolutely realistic):

1. Please evaluate the realism of simulating sternal elevation using Rultract:
    1) Interface and ease of use.
    2) Responsiveness of simulation to sternal elevation.
    3) Effect of sternal elevation on improving thoracoscopy and relieving pressure on pericardium.
2. Please evaluate the realism of organ simulation and visualization:
    1) Pericardium.
    2) Mediastinal tissue.
    3) Lungs.
    4) Ribcage and internal intercostal muscle.
    5) Diaphragm.
3. Please evaluate the realism of the mediastinal dissection process.
    1) Tactility of physical skin and muscle on manikin.
    2) Simulated organ deformation upon collision.
    3) Tactility and haptic feedback of virtual simulated organs.
    4) Responsiveness and experience during mediastinal dissection.

5) Quality of thoracoscopic view.

4. Please evaluate the overall realism of the NPST.

    1) First impression.

    2) User design.

    3) Introducer manipulation.

    4) Synchronization between physical and virtual components.

    5) Overall impression and realism.

PART II: Please evaluate the **training capacity** of the NPST system and its components. (1-absolutely not realistic, 4-neutral, 7-absolutely useful):

1. Please evaluate the training capacity for identifying procedural landmarks using visual and tactile cues (relevant to NP):

    1) Deepest point of depression.

    2) Intercostal spaces.

    3) Anterior axillary line (AAL).

    4) Mid axillary line (MAL).

    5) Incision site.

    6) Entry and exit sites of internal intercostal muscle.

    7) Overall.

2. Please evaluate the training capacity for sternal elevation:

    1) Attaching Rultract to sternum.

    2) Lifting sternum and improving thoracoscopic view.

    3) Overall.

3. Please evaluate the training capacity for mediastinal dissection steps:

    1) Orientation.

    2) Finding correct tunneling plane.

    3) Avoiding tip/pericardium collision.

    4) Pawing down on pericardium to separate from sternum.

    5) Successful substernal tunnel creation.

    6) Overall.

4. Please evaluate the overall training capacity of the NPST:

    1) Training of Introducer manipulation.

    2) Training of hand-eye coordination.

    3) Training of special properties of the Nuss procedure.

    4) Overall training capacity.

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Educational Background

Ph.D.	: August 2017, Old Dominion University, Norfolk, VA, USA
Major	: Modeling and Simulation
Thesis	: *Development and Validation of a Hybrid Virtual/Physical Nuss Procedure Surgical Trainer.*
M.Sc.	: August 2013, Old Dominion University, Norfolk, VA, USA
Major	: Modeling and Simulation
Thesis	: *A Multi-Configuration Display Methodology Incorporating Reflection for Real-Time Haptic-Interactive Virtual Environments.*
B.Sc.	: June 2011, German-Jordanian University, Amman, Jordan
Major	: Industrial Engineering
Thesis	: *Utilizing Lean Principles for Changeover Time Reduction at Hikma Pharmaceuticals.*

Publications

***Book Sections*:**

- Qi Zeng; Nahom Kidane; **Mohammad F. Obeid**; Chenghao Chen; Ruofan Shen; Robert E. Kelly; and Frederic D. McKenzie, "Utilizing Pre- and Postoperative CT to Validate an Instrument for Quantifying Pectus Excavatum Severity," In: *Communications in Computer and Information Science: Theory, Methodology, Tools and Applications for Modeling and Simulation of Complex Systems*, vol. 645, pp. 451-456, 2016.
- **Mohammad F. Obeid**; Nahom Kidane; Krzysztof J. Rechowicz; Salim Chemlal; Robert E. Kelly; and Frederic D. McKenzie, "Validation of an objective assessment instrument for non-surgical treatments of chest wall deformities," In: *Studies in Health Technology and Informatics*, vol. 22, pp. 273-280, 2016.
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- **Mohammad F. Obeid**; Nahom Kidane; Qi Zeng; Chenghao Chen; Robert E. Kelly; and Frederic D. McKenzie, “External Severity Indices for Quantifying Pectus Excavatum Validated Using Pre- and Postoperative CT Analysis,” In: *Journal of Pediatric Surgical Specialties*, vol. 10 (1), 2016.
- Qi Zeng; **Mohammad F. Obeid**; Nahom Kidane; Chenghao Chen; Robert E. Kelly; and Frederic D. McKenzie, “Pre- and Postoperative Nuss Procedure CT Analysis for Assessing Pectus Excavatum Indices,” In: *Journal of Pediatric Surgical Specialties*, vol. 10 (1), 2016.
- Krzysztof J. Rechowicz; **Mohammad F. Obeid**; Salim Chemlal; and Frederic D. McKenzie, "Simulation of the critical steps of the Nuss procedure," *Computer Methods in Biomechanics and Biomedical Engineering: Imaging & Visualization*, vol 3, Issue 4, pp. 189-203, 2014.
- Mariam Kotachi; Ghaith Rabadi; and **Mohammad F. Obeid**, "Simulation Modeling and Analysis of Complex Port Operations with Multimodal Transportation," In *Procedia Computer Science*, vol. 20, pp. 229-234, 2013.

***Conference Proceedings*:**

- Mahmoud Khasawneh; Tariq Tashtoush; Raed Jaradat; Sawsan Abutabenjeh; **Mohammad F. Obeid** “Modeling and Simulation for Public Policy Decision-Making: A Preliminary Causal Loop for the Case Study of Legalized Abortion and Crime,” In: *Proceedings of the 2017 Industrial and Systems Engineering Conference*, 2017.
- **Mohammad F. Obeid**; Robert Obermeyer; Nahom Kidane; Robert E. Kelly; and Frederic D. McKenzie, “Investigating the Fidelity of an Improvement-Assessment Tool after One Vacuum Bell Treatment Session,” In: *Proc. of the 2016 Summer Simulation Multiconference*, 2016.
- **Mohammad F. Obeid**; Krzysztof J. Rechowicz; and Frederic D. McKenzie, "Incorporating Reflection for Real-Time Multi-Configuration Haptic-Interactive Virtual Environments," In: *Proc. of the 2014 Summer Simulation Multiconference*, 2014.

- **Mohammad F. Obeid** and John Shull, "West Nile Virus system dynamics investigation in Dallas County, TX," In: *Proc. of the 2013 Winter Simulation Conference (WSC)*, pp. 2076-2087, 2013.

***Posters, Abstracts, and Formal Presentations*:**

- **Mohammad F. Obeid**; Robert E. Kelly; and Frederic D. McKenzie, "Development of a Hybrid Virtual/Physical Nuss Procedure Surgical Trainer," at the *International Workshop on Augmented Environments for Computer-Assisted Interventions,* held in conjunction with *Medical Image Computing and Computer Assisted Interventions (MICCAI) Conference*, in Quebec City, Canada, September 2017.
- **Mohammad F. Obeid**; Nahom Kidane; and Frederic D. McKenzie, "Pectus Metric Tool for Evaluating Chest Wall Deformities" at the *MODSIM World Conference M&S Challenge Competition*, Virginia Beach, USA, April 2017.
- **Mohammad F. Obeid**; Nahom Kidane; and Frederic D. McKenzie, "An Instrument for Assessing Chest Wall Deformities and Improvements" at the *Spring Simulation Multi-Conference (SpringSim)*, Virginia Beach, USA, April 2017.
- Qi Zeng; Nahom Kidane; **Mohammad F. Obeid**; Chenghao Chen; Ruofan Shen; Robert E. Kelly; and Frederic D. McKenzie, "Poster: Pre- and Postoperative CT Validation of an Instrument for Quantifying Improvement after Pectus Excavatum Surgery", at the *5th World Congress of Pediatric Surgery (WOFAPS)*, Washington, DC, USA, 2016.
- Qi Zeng, **Mohammad F. Obeid**, Nahom Kidane, Chenghao Chen, Robert E. Kelly, and Frederic D. McKenzie, "External Severity Indices for Quantifying Pectus Excavatum Validated Using Pre- and Postoperative CT Analysis", at the *Chest Wall International Group Annual Meeting (CWIG)*, Norfolk, USA, June 2016.
- Nahom Kidane, **Mohammad F. Obeid**, Krzysztof J. Rechowicz, Robert E. Kelly, Salim Chemlal, and Frederic D. McKenzie, "Mobile Application for Objective Measurement of Pectus Excavatum Vacuum Bell Treatment" at the *Spring Simulation Multi-Conference (SpringSim),* Alexandria, USA, April 2015.
- Yu Chih Hung; Dwayne Morris; Annabelle Poston; Jordan Goodmurphy; Miro Kirov; Michelle Dominado; Anna Fletcher; Frederick D. Mckenzie; Eun-sil Heo; Shao-Hui Chang; **Mohammad F. Obeid**; and Craig Goodmurphy, "Combining 3D Printing and CT Scanning in the Production of Obstetrical Ultrasound Phantoms for Undergraduate Medical Education" at: the *3rd Annual World Congress on Ultrasound in Medical Education (WCUME)*, October 10th 2014, Portland, Oregon, USA.
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