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During the course of this cooperative agreement, the research team built a real-time, man-in-the-loop, sinus surgery simulator. The simulator underwent months of evaluation. Preliminary formative evaluation results yielded suggestions for simulator enhancement. Where possible, the team implemented those suggestions. More rigorous summative evaluation efforts measure and document a statistically significant correlation between simulator scores and endoscopic surgical experience. This research is an important step in the technological evolution of surgical simulation in the virtual reality training environment. It coincides with the Army's quest for training that maximizes the use of emerging technologies in computer simulation, and virtual reality.

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INTRODUCTION

Subject

Through cooperative agreement DAMD17-95-2-5023, the research team sought to build and evaluate an endoscopic sinus surgery simulator.

Purpose

The purpose of this cooperative agreement is to find answers to the following:

- Can surgical simulation enhance the comprehension and performance of minimally invasive surgical procedures?
- Are objective performances of simulated surgeries useful in the evaluation of surgical competence?
- What levels of visual complexity and tactile response are necessary to achieve enhanced training?
- Can the above objectives be achieved at an acceptable cost?

Scope

This research comprises two parts. Technological advances are required to create a state-of-the-art simulator for training endoscopic sinus surgery procedures. In general, these advances can be categorized into haptic technology, patient model development, and simulation modeling. Especially demanding is surgical interaction between surgical instruments and patient tissues. There is also the question of the efficacy of augmented virtual reality devices in training surgical procedures. Specifically, can an endoscopic sinus surgery simulator improve surgical skill?

Background

Surgical simulation for physician training is a recent development. Research thus far includes simulation for a variety of medical procedures, including abdominal laparoscopy (1-4), limb surgery (5-6), eye surgery (7-8), plastic surgery (9), gastrointestinal endoscopy (10-13), and epidural anesthesiology (14).

Colonoscopy, flexible sigmoidoscopy and epidural simulators have employed haptic systems. The approach taken is highly dependent on the specific requirements of the simulator. Haptic technology is attracting considerable interest (14-17).

Visual cues must be carefully selected for rendering the virtual patient's anatomy (18). There are a variety of approaches to synthetic image generation that affect the rendered image. The mainstream rendering technique is conventional computer graphics. This approach uses high-performance graphics hardware to render visual texture mapped onto polygonal surfaces. Other approaches render volumetric data (19). Noar and Beer-Gabel employ videodisk technology using images acquired during live procedures. This technique requires many thousands of actual endoscopic images and produces superb realism, but the loss of operator ability to freely dissect patient tissue makes this method unreasonable for sinus

surgery. Noar is attempting to combine videodisk technology with computer graphics imaging (20). Other approaches to visual simulation are possible (11, 21).

Modeling of tissue deformation to simulate the interaction between a surgical instrument and the patient model is in itself a burgeoning field. Cover provides a review of the state of the art in mathematical deformation models (1).

High-fidelity simulators have a proven record of increasing the readiness of military and commercial flight crews. They hold similar promise for the medical field. While computer simulation offers the potential for standardized training and skill assessment without direct patient involvement (22), the medical simulation industry has published no data supporting that claim. This project is unique in attempting to measure training transfer from a high-fidelity, procedure-specific simulator.

Readiness is the very reason for the existence of military medicine. The General Accounting Office (GAO) cites that in support of the Persian Gulf War, medical personnel ". . . were not qualified in the specialties to which they were assigned, were not physically able to perform their jobs, did not have proper medical credentialing documents, or had not completed training." (23) The Department of Defense (DoD), in response to these deficiencies, enacted a new policy requiring medical readiness (24). The DoD directed the armed services to utilize readiness training programs that include "realistic and skills training and maximize the use of emerging technology such as distance learning, computer simulation, and virtual reality" (24). The efficacy of such devices in medical training is a fundamental issue that requires systematic analysis.

In summary, the emerging field of virtual reality and medical simulation brings promising new embryonic technology that, if properly applied, may lead to enhanced medical training and readiness. To date, there has been no measurement of the training effectiveness of these devices. This cooperative agreement applies the latest technology toward the goal of developing and measuring the effectiveness of an endoscopic sinus surgery simulator.

BODY

Experimental Methods and Approach

The research team comprised the following individuals and institutions, each with a unique purpose as given below:

TEAM MEMBER	RESPONSIBILITIES
Lockheed Martin	Lockheed Martin, prime contractor for the cooperative agreement: • Performed the simulator systems engineering task • Defined the software architecture • Developed software for rendering, contact detection, dissection, tissue deformation, CT display, student evaluation, and computer-aided instruction • Developed the instrument models Lockheed Martin integrated the major components, including the simulation computer, its software, the tactile feedback subsystem and patient models.
The Madigan Army Medical Center (MAMC)	MAMC provided a subject matter expert (SME) in the field of sinus surgery. Lieutenant Colonel Charles Edmond MD was responsible for overseeing all phases of requirements analysis, design, development, implementation and evaluation.
Immersion Corporation	Immersion Corporation developed the tactile feedback prototype.
Ohio Supercomputer Center (OSC)	OSC developed the standard virtual patient model and a battlefield trauma case.
Human Interface Technology Laboratory (HIT Lab) at the University of Washington	Working with MAMC, the HIT Lab conducted the evaluation of endoscopic image synthesis fidelity and completed evaluations, human factors activity, and the "summative" evaluations at project completion. Because the HIT Lab provided no material component to the simulator itself, it could evaluate the simulator without bias.
Mr. Robert Johnston	Mr. Johnston consulted on the establishment of design parameters for the simulator.
Mr. Robert Eisler	Mr. Eisler consulted on modeling ballistic injury.

In this report, "development team" refers to those institutions that focused primarily on simulator development, including Lockheed Martin, the Immersion Corporation, OSC, and Robert Eisler. The phrase "evaluation team" includes those individuals and institutions that focused primarily on the simulator evaluation, i.e., MAMC, the HIT Lab, and Robert Johnston.

During Phase I of the two-phase cooperative agreement, the first 18 months, the development team created a simulator to serve as a platform for evaluation and further

enhancement. Developmental items include a model of the human sinus anatomy, a system to track surgical instruments, and simulation software.

During Phase II, the last six months of the agreement, the HIT Lab and MAMC evaluated the simulator at their respective locations. Simulator development continued with the implementation of the evaluation team's suggestions.

Spiral software development techniques resulted in a working simulator early in the project and increased its capabilities incrementally. The C++ simulator software, developed according to current object-oriented design principles, created a robust foundation for iterative refinement in response to simulator evaluation.

Prior to Phase II, the evaluation team developed criteria to assess simulator functions with respect to training efficacy. At the beginning of Phase II, after simulator deployment, several subjects used the simulator to provide information about its usability and success in training. Refinements to the simulator reflected results of this formative evaluation prior to formal data acquisition. After the initial refinements, evaluators used a frozen simulator configuration to acquire data from as many subjects as were available.

Dr. Charles Edmond established performance criteria which guided the incorporation of multi-level training scenarios and computer-automated student assessment into the simulator. The evaluation team gathered data using five standard techniques:

- Observation
- Performance testing
- Think-aloud
- Audit trails
- Debriefing

They observed the subjects to see how well they performed critical tasks at novice, intermediate and advanced levels. The simulator computed scores based on the established performance criteria. Subjects verbalized their thoughts while performing simulator tasks. Video cameras recorded each procedure. Further, the simulator recorded the subjects' actions and numerical scores to facilitate a thorough analysis of student performance. Post-trial interviews determined what was difficult, easy, successful, unsuccessful, preferred, and disliked. Analysis of data gathered by these procedures will guide further revision and development.

Investigators solicited subjects from three distinct groups:

- Non-MDs with general intelligence and psychomotor abilities roughly comparable to the average otolaryngologist
- Non-ENT physicians from a variety of specialties
- ENTs with wide-ranging ESS experience

Investigators focused on these three groups to establish a baseline and asymptote for the evaluation of the efficacy of the simulator in training otolaryngology residents. The first two groups also allowed a "shakedown" of the system and research protocols without using valuable ENT resident subjects, and provided baseline scores for subjects unfamiliar with ENT procedures. Finally, the non-ENT physician group could provide valuable input about the extensibility of the simulator to non-ENT applications.

Twelve volunteers from the University of Washington College of Engineering comprised the non-MD group. These subjects ranged in age from 23 to 54, and included graduate students, professional staff and faculty. All had had some experience with simulation and virtual reality. None had previously used an endoscope or attended medical school.

Eight University of Washington MDs from specialties other than otolaryngology provided extensive feedback on the simulator design and utility for other medical and surgical tasks: three video-endoscopic surgeons, two radiologists, a neurosurgeon, a cardiologist, and an anesthesiologist. Four of these subjects also provided us with complete trial performance data.

Twelve staff and resident ENTs (1 female, 11 males) from MAMC served as subjects. Subjects in this group ranged in age from 28 to 46, with a mean age of 35.2 years, and a standard deviation of 6.15 years. One was left-handed, 10 were right-handed, and the handedness of one was unknown. ENT experience for this group broke down as follows:

- Staff (averaging five years of training, six years of practice and more than 100 ESS procedures performed)
- R2s (with an average of 1-5 ESS procedures performed or observed)
- R3 (with 6-20 ESS procedures performed or observed)
- R4s (with an average of 21-100 ESS procedures performed or observed)
- R5s (with an average of 21-100 ESS procedures performed or observed)

Assumptions

None.

Procedures

Investigators followed data collection procedures approved by their respective Internal Review Boards (IRBs). IRBs at MAMC and The University of Washington approved protocols for data collection.

To begin, investigators briefed the subjects on the procedure. Each subject signed an IRB-approved consent form and completed a pre-trial questionnaire, providing information about their background and experience that might be relevant to their performance.

A video camera recorded the procedure from that point forward. Investigators familiarized each subject with the simulator, providing techniques for handling the instruments. Subjects watched as the simulator demonstrated the actions they were to perform. Investigators

encouraged subjects to think aloud, prepared the simulator to capture the subject's actions, and started the simulation. The subjects performed the trial while the videotape and simulator recorded their actions. Upon completion of the exercise, the simulator stored student actions and scores to disk and the subjects completed post-trial questionnaires.

RESULTS AND DISCUSSION

The Simulator – Technical Overview

The simulator allows performance of limited endoscopic sinus surgery on a virtual patient using replicas of an endoscope and other surgical instruments. The student surgeon freely explores the virtual anatomy by manipulating the simulated endoscope. Using a simulated needle, the student injects a vasoconstrictor into sinus tissue, causing it to blanch. The student displaces the middle turbinate toward the septum with a simulated freer, gaining access to deeper recesses of the sinus cavity. The student dissects the ethmoid bulla, middle turbinate, anterior ethmoid cells, uncinate process, sphenoid ostium and maxillary ostium with any of a dozen dissection instruments. All instruments except the endoscope provide force feedback in three axes, allowing the student to feel virtual tissue through the instrument's handle.

The student starts training with an abstract novice environment instead of a virtual patient. Using this environment, the student performs tasks and becomes familiar with the suite of surgical tools. This novice-level training improves hand-eye coordination through immersive experience. When ready, the student moves to intermediate-level training where abstract training aids appear in the context of sinus anatomy. Aids for navigation and injection are identical to their novice-level counterparts. They prompt the student to perform the appropriate tasks while learning the anatomy. At the advanced level, the student performs surgical procedures without the benefit of abstract computer-based aids.

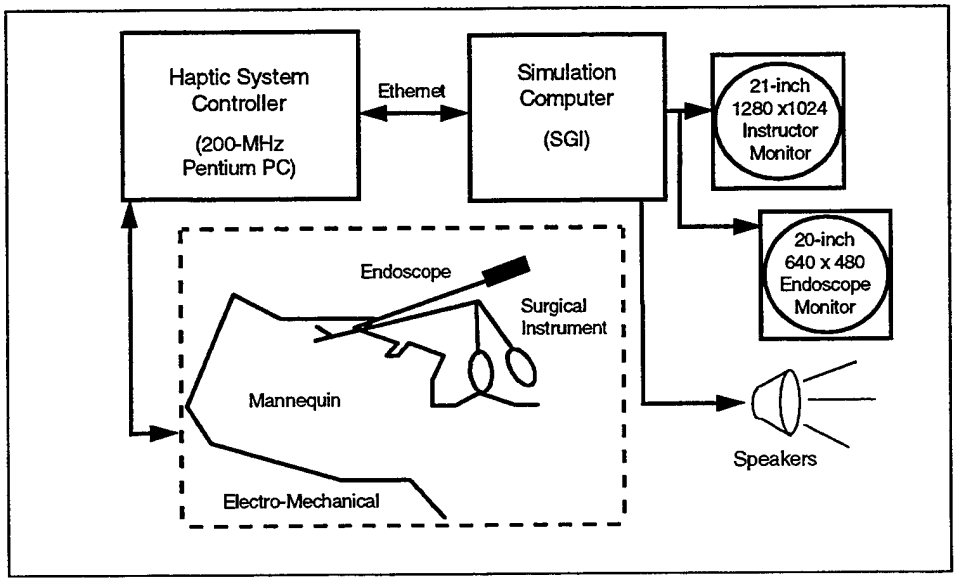


Figure 1. Endoscopic Surgical Simulator Components

Figure 1 illustrates the principal components of the endoscopic sinus surgery simulator. The system has two computers linked by an Ethernet interface. A Silicon Graphics Incorporated (SGI) computer serves as the simulation host platform. The haptic system controller PC performs high-rate software control over replicas of surgical instruments. The simulator's

endoscope monitor is similar to that used in an operating room. A separate instructor monitor displays a graphical user interface for control of the simulation. Speakers provide audible feedback to the student.

The endoscopic simulator is shown in operation in Figure 2. The student manipulates the endoscope using his right hand to control its position and orientation. As the endoscope moves, its monitor displays the anatomy from the vantage of the endoscope tip. (The endoscope is not visible in the monitor, just as a video camera is not visible in its own video.) The student holds the endoscope in a position to view the surgery and simultaneously, with his left hand in a scissors-like grip, manipulates the surgical instrument. He steadies the virtual surgical instrument within the field of view of the endoscope and operates on the virtual anatomy. The student senses it by touch, and then injects, displaces or dissects it. He "feels" the virtual anatomy through forces applied by the electro-mechanical haptic system. The view in the endoscope monitor continually updates as he manipulates the endoscope and surgical instrument.

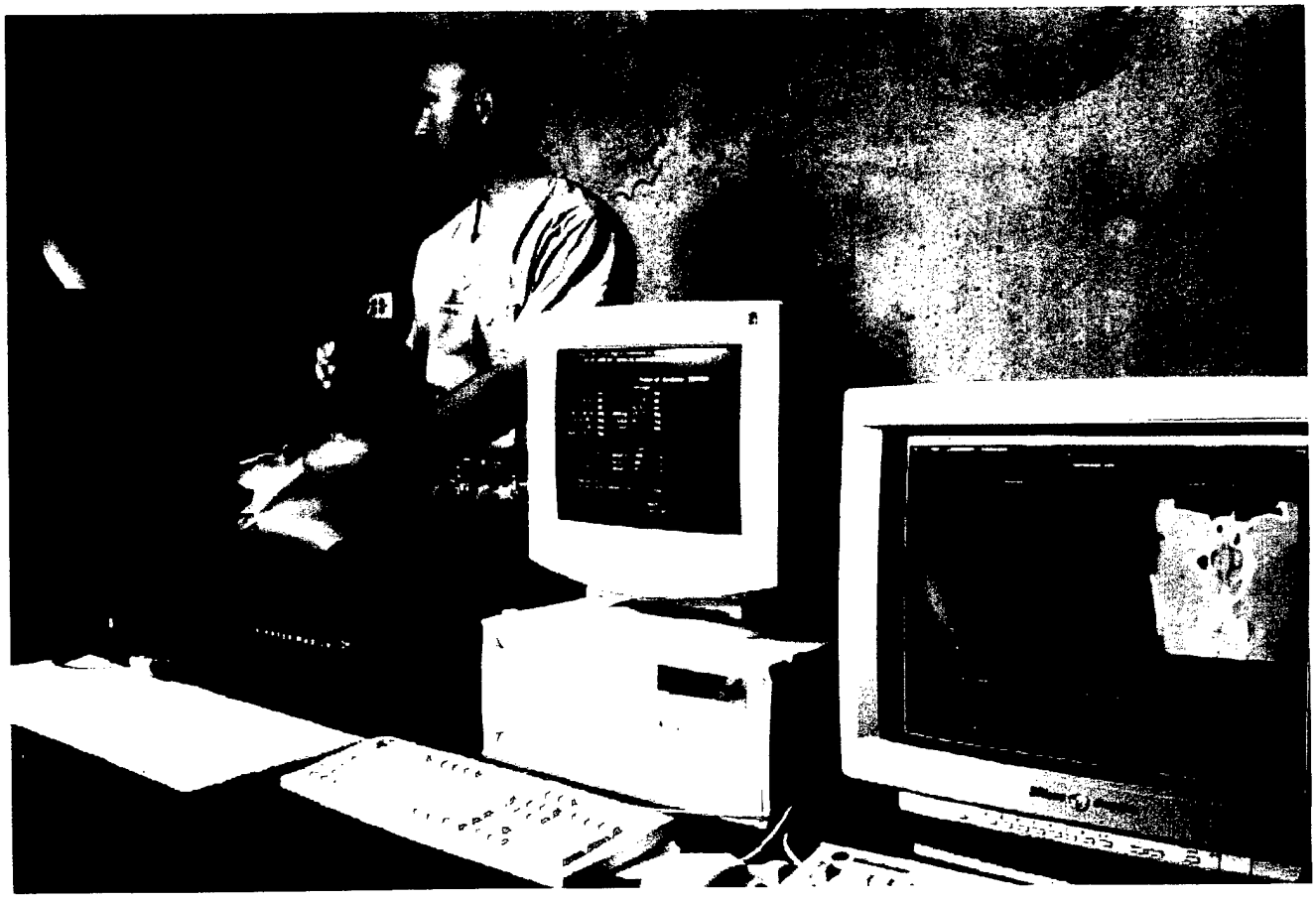


Figure 2. Endoscopic Surgical Simulator in Action

The Simulator – Endoscope Monitor

The endoscope monitor, shown in the upper left corner of Figure 2, displays images as seen through the virtual endoscope. The 20-inch monitor, of the type used in an operating room, is driven by the simulation computer with a color-composite 480 x 640 signal identical to the operating room video format.

The Simulator – Haptic System

The haptic system comprises a high-speed Pentium computer and an electro-mechanical component (Figure 3). It tracks the position and orientation of the endoscope through a mechanical apparatus external to the mannequin's head, and tracks another surgical instrument via a second mechanical apparatus inside the mannequin's head. The haptic system monitors the closure state of the instrument's scissors-like grip. As the user manipulates these physical replicas of an endoscope and surgical instrument, the connected electro-mechanical hardware senses their position and orientation in all six degrees of freedom. The haptic system PC reads and transfers the complete state of both tools to the simulation computer. The haptic system applies force in three axes to the distal tip of the surgical tool, simulating haptic cues associated with surgery.

Investigators gave the name "Impulse Engine 3 Grounded Motors" (3GM) to the apparatus that simulates forces on the surgical instrument because the apparatus incorporates a revolutionary design to support all the motors by the ground. This approach gives the mechanism low weight and inertia. Investigators also optimized the device for the workspace inside the mannequin's head. The 3GM supplies at least 4 Newtons of force display in three dimensions, low inertia and backlash, and six dimensions of location sensing. Sinus surgery is inherently a 3D application. Higher degrees of freedom, used to display torques, are not necessary because most forces encountered during surgery occur at the tool's tip.

To obtain 3 degrees of freedom, the device is essentially a five-bar mechanism (which is 2D) with an additional axis of rotation. A gimbal that attaches the surgical instrument to the endpoint of the 3GM adds three degrees of rotation. These joints also use encoders and capstan drives and are as small as possible, limiting interference with the inside of the model head. They are mechanically robust, and provide angular swings of at least 30° in each direction. An analog Hall Effect sensor with a resolution of better than 1° measures the angle of the scissors-like grip on the tool. The 3GM and gimbal have resolutions of 0.1 mm and 0.3°, respectively. A haptic display should have low inertia in an attempt to make the user unaware of the presence of the device. Force feedback cannot compensate for inertia because this would require instantaneous acceleration measurements. A twisting cable design allows grounding of all three motors, yielding a low inertia device. The linkages are lightweight carbon fiber and aluminum parts. Zero backlash is another requirement for a "transparent" device. A cable drive system makes a very smooth transmission, with virtually no friction and backlash. Encoder readings at each joint and forward kinematics calculate the position of the endpoint of the surgical instrument in real time.

Figure 3. Electro-Mechanical Haptic System Component

The haptic system does not apply force to the replica of the endoscope. The endoscope replica connects to a commercially available microscribe from Immersion Corporation. Investigators modified the microscribe,placing an endoscope replica at its tip and adding a roll sensor.

The 200-MHz Pentium PC dedicated to the haptic system provides high bandwidth force updates at rates exceeding 3000 Hz. This minimizes latencies in force calculations, and results in a stable force that is stiffer than would be possible at lower iteration rates. It communicates the surgical movements to the simulation computer sixty times per second. At simulation computer display rates, the haptic system receives a simplified patient model in the neighborhood of the tip of the surgical instrument. That neighborhood model becomes the patient for the purpose of force calculations. Using this approach, the student can freely explore and sense by touch the entire patient anatomy.

The Simulator – Haptic System Software

The patient model comprises over 25,000 surfaces. Manipulation of the sinus tissue through dissection, injection, and deformation applies to more than 50% of the modeled sinus surface. The haptic system must interact with these surfaces at extremely high iteration rates to provide even moderate stiffness. To aid the haptic computer in this task, the simulation computer simplifies the patient model to a box in the neighborhood of the surgical tool's tip. Every frame, 15 to 60 Hz, the simulation computer senses the location of the patient model from the vantage point of the tool tip by "looking" to the left, right, up, down, and straight ahead. It creates one plane that is perpendicular to each of the five sensing line segments and sends the resultant five-plane model to the haptic computer. The haptic computer receives the updated five-plane model and uses it for surgical tool interaction until another model arrives in 17 to 67 milliseconds (ms). Based on this model, the haptic computer controls the forces applied by the motors at rates exceeding 3000 Hz. With this approach, the student can feel any part of the simulated anatomy without restriction.

The system simulates a range of stiffness based upon the CT density. Very bright or dense CT objects are stiffer than dark objects. Ultimately, Dr. Edmond drew from his clinical experience, choosing to minimize the range of stiffness between hard and soft tissue. Even the maximum stiffness obtainable through the haptic system felt like mid-range sinus tissue.

Sinus tissues vary in stiffness from soft to bony structures. Surgeons palpate these with surgical instruments to aid in differentiating among sinus structures. While the development team considered this to be important tactile feedback, the haptic device did not supply enough stiffness to simulate the feel of dense bone, and attempts to simulate it resulted in vibration and instability.

As the cooperative agreement progressed, the importance of palpation cues diminished in relation to the importance of tool-specific haptic responses. For example, a needle that penetrates tissue should "stick," reassuring the student that injection can occur. Haptic forces then hold the needle's tip in place. Without this haptic support, some students simply could not inject targets in the novice model.

As another example, the distal tip of a forceps grabs tissue as it dissects, holding itself steady during the dissection. Without this tool-specific response, students had difficulty steadying the tip during dissection. The simulator also mimics the vibration of the microdebrider. That vibration increases as the tool encounters tissue, reassuring the student of tool position when the only other position information comes through the monocular endoscope.

Although the haptic device fell short of its goal to provide distinguishable palpation among a variety of tissue types, determination of tool location by touch and tool-specific haptic responses justifies its expense.

The Simulator – Simulation Computer

The simulation computer is the heart of the endoscopic sinus surgery simulator. It incorporates an Onyx computer with four R4400 CPUs and Reality Engine II graphics. The real-time simulation software senses the computer configuration, dynamically configuring itself to take full advantage of its hardware. For example, upon sensing four CPUs, the real-time simulation software spawns four parallel processes, one for each CPU. Simulator latency differs widely, depending on number of CPUs and frame rate. Frame rate in turn depends upon number of CPUs, system architecture, graphics speed, and CPU speed.

The Simulator – Instructor Monitor

The 21-inch instructor monitor is an integral part of the simulation computer. When the simulator is off-line, the monitor serves as the display for software development and UNIX administration tasks. When the simulator is active, simulation software takes over the display and presents both the endoscope view and the graphical simulation control interface.

The instructor interface provides control of the simulation state, instrument selection and patient selection. It runs as a separate UNIX X-window application using Motif Widgets. The instructor display is depicted in Figure 4. The circular window (left) is the endoscope camera view, which is created under control of the real-time simulation process. This window appears in the instructor monitor as shown in the figure, but also comprises the entire view at the endoscope monitor, as it would in the operating room. The interface permits the user to select an endoscope with standard offset angles, and choose one of 15 surgical instruments. It displays and provides control of the simulator state. A pop-up configuration window allows selection of a patient model, student, proctor, or recorded procedure for playback.

In current medical practice, surgeons routinely scan patients prior to surgery to obtain computer tomography (CT) images. They study the images before and during the surgery. Using a recent innovation called image-guided surgery, technicians spatially register surgical instruments to the patient. The image-guided surgery device fetches digitized CT images in the plane of the instrument and displays them on a workstation to aid the surgeon's spatial awareness. The simulator implements this feature in the following manner. The haptic system tracks the surgical instruments in the patient coordinates. The graphical user interface retrieves the coronal CT image of the plane nearest to the tip of the selected surgical tool. A cursor marks the tool's position within the CT image. This feature is similar to commercially available image-guided surgical devices. Figure 4 shows the CT slice on the right side of the display.

The Simulator – Speakers

Stereo speakers and a sound card supply audible feedback to the student, in the form of the sounds of a heart monitor and recorded voice messages. The messages coach and report progress to the student.

The Simulator – Heart Monitor

The heart monitor portion of the simulation generates audible beeps similar to operating room equipment. Upon injection of virtual patient anatomy, the heart rate increases rapidly and gradually returns to normal. Instructors may force an abnormally high rate to test student awareness.

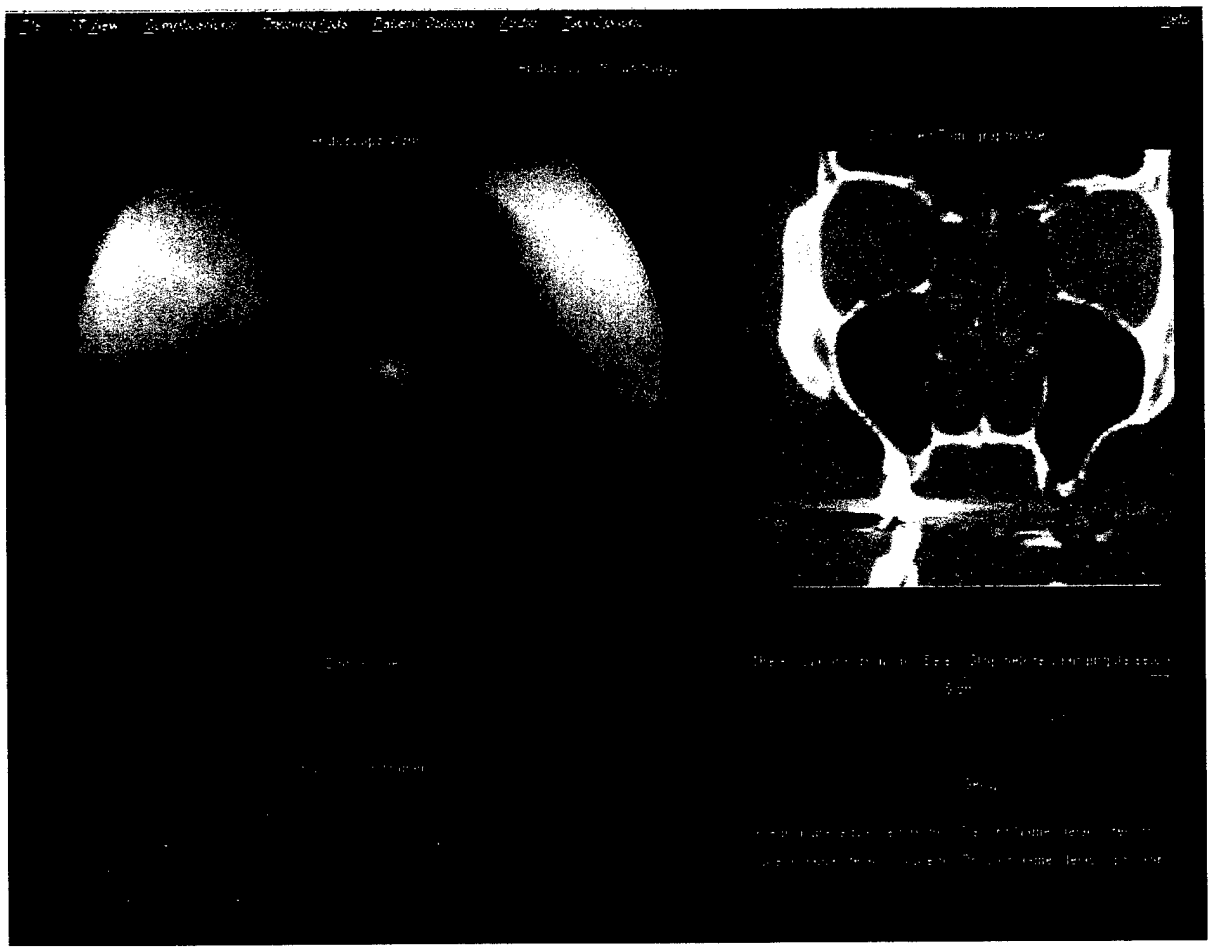


Figure 4. Instructor Monitor - User Interface

The Simulator – Rendering Approach

Rendering the patient and tool models came down to two alternatives, the volumetric approach and polygonal rendering. To decide, one must consider image quality, rendering

speed, and ease of data manipulation to simulate surgical interaction. Voxel-based image quality degrades at close view and rendering speed can be slow (25). Polygonal rendering delivers superior quality images at higher display rates. Recognition of and navigation through the anatomy is critical in sinus surgery, and cannot be adequately simulated using volume rendering. An advantage of volumetric data sets is that dissection mathematically reduces the removal of voxels through table look-up. There may be no advantage for tissue deformation with either approach. Early in the program, the development team spoke with computer graphics expert Jeff Roberts, manager of SGI's Visualization Technical Center in Farmington, MI. He offered advice on current rendering rates and capabilities of SGI volume rendering software versus polygon rendering software. At the conclusion of that meeting, the development team decided to use polygons.

Volumetric rendering may become appropriate for surgical simulation in the near future. SGI specifies both volumetric and polygonal capacity for their products. This would indicate that the computer industry is starting to recognize the importance of volume-based rendering. Currently, however, volume rendering does not adequately represent the entire sinus cavity in real time, without loss of detail.

The simulator uses Performer,™ an SGI software layer built upon the industry standard Open GL. Immaturity, lack of speed and fuzzy images disqualified volume-based rendering techniques.

Investigators attempted to simulate the endoscope image as closely as possible to its appearance during an actual procedure. The image fidelity demands of the endoscopic surgery are significant and differ sharply with flight simulation and conventional virtual reality applications. Unlike simulating terrain on a flight simulator, the close proximity of the anatomical structures causes a high percentage of the polygons that represent the sinuses to fall simultaneously within the viewing frustum. This places a heavy load on the simulation computer and graphics hardware. All illumination originates from the endoscope, creating an image with a high degree of depth attenuation. Fortunately, shadowing is unnecessary because of the co-linearity between the imaging optics and the light source. The anatomy is moist and reflective, creating numerous conspicuous specular highlights which yield important depth cues. Investigators applied high-quality visual texture to the geometry of the virtual patient, generated from the surface reconstruction of the Visible Human Project data.

Rendering the complex sinus anatomy requires thousands of shaded texture-mapped polygons. This results in poor real-time performance even for expensive state-of-the-art graphics hardware. To address this concern, the development team optimized the rendering algorithm by limiting the yon plane of the viewing frustum to a distance of 25 mm, which is the minimum distance Dr. Edmond accepted. Rendering software culls out structures that are outside the viewing frustum. This yielded a substantial improvement in rendering speed.

Another gain in performance resulted from hierarchical organization of patient model polygons. Simulation software collects polygons that are close to one another in space, enclosing them in a sphere for testing against the viewing frustum. Simulation software further compiles these collections into higher level groups, forming a tree with a sphere at

each node. Investigators found that a tree with 5 to 8 levels yields optimal performance. A simple test of any sphere against the viewing frustum may discard that node and all of its descendants from processing by the rendering pipeline. The same hierarchy allows efficient tree traversal for surgical interaction.

The Simulator – Latency

Two primary factors determine the quality of the simulation, latency and patient model fidelity. For purposes of this discussion, patient model fidelity equates to the number of polygons on the patient model. Latency is the time from instrument movement to the change in its display at the endoscope monitor. Latency and fidelity are inversely proportional. Flight simulation experience has led to a demand of latency of less than 100 ms. Early in the course of this cooperative agreement, the goal of a 100-ms latency drove the simulator design.

In the evaluation phase, Dr. Edmond tested patient models that varied the load on the simulation computer. He preferred to relax the latency requirement in favor of higher fidelity anatomical models. The tested system, deemed acceptable by Dr. Edmond, has a latency in the range of 200 ms and a 20-Hz iteration rate. Using this device, the evaluation team did not observe any phenomena such as pilot-induced oscillation that is common in flight simulators with poor response. It is possible to conclude that the slow, deliberate surgical motion used in sinus surgery allows a higher latency than may be tolerated in flight simulators.

The Simulator – Surgical Interactions

Flight simulator databases consist primarily of terrain whose elevation is a function of latitude and longitude. (The industry refers to this as 2.5D.) The user cannot manipulate the environment. Surgical simulation is far more demanding. The viewing frustum may enclose numerous overlapping hidden surfaces that represent complex sinus cavities. The rendering pipeline uses much of its bandwidth to process them, even though they contribute nothing to the rendered image. Tissue manipulation also challenges the capabilities of simulation technology. The sinus cavity must be fully three-dimensional (3D), with infinite possibilities for alteration by removal or manipulation of tissue.

In the object-oriented software design, the surgical interactions are methods of the software objects that make up the patient model. Each anatomical object responds to surgical manipulation with its own dissection and deformation methods. This facilitates tailoring behavior for each of the various tissues of interest. The simulator implements dissection in a limited way by causing tissue to vanish when dissected, exposing bone fragments for the student to extract.

Bleeding simplifies to a limited number of "bleeders." Upon dissection of a bleeder, a textured blood-red sphere begins to grow, its volume increasing uniformly with time. The spheres reduce in size when in contact with one of the suction instruments. Each sphere immediately degrades the visibility through the endoscope on contact, necessitating the wiping of the endoscope on a pad placed on the forehead of the mannequin. These simplifications do not significantly compromise training and a fully realistic simulation would be a difficult undertaking. Figure 5 depicts the removal of bone chips in dissection and the growth of a bleeder.

Figure 5. Bone Chips and Bleeder

The ethmoid sinuses consist of hollow cells made of eggshell-like bone. The bulla is the prominent anterior cell. Simulated dissection occurs within the dissection volume of the surgical instrument, deleting vertices and their associated polygons and exposing the internal surface of the cell. Figure 6 depicts the microdebrider dissecting the ethmoid bulla. The far-right image shows additional ethmoid cells exposed by removal of the entire bulla.

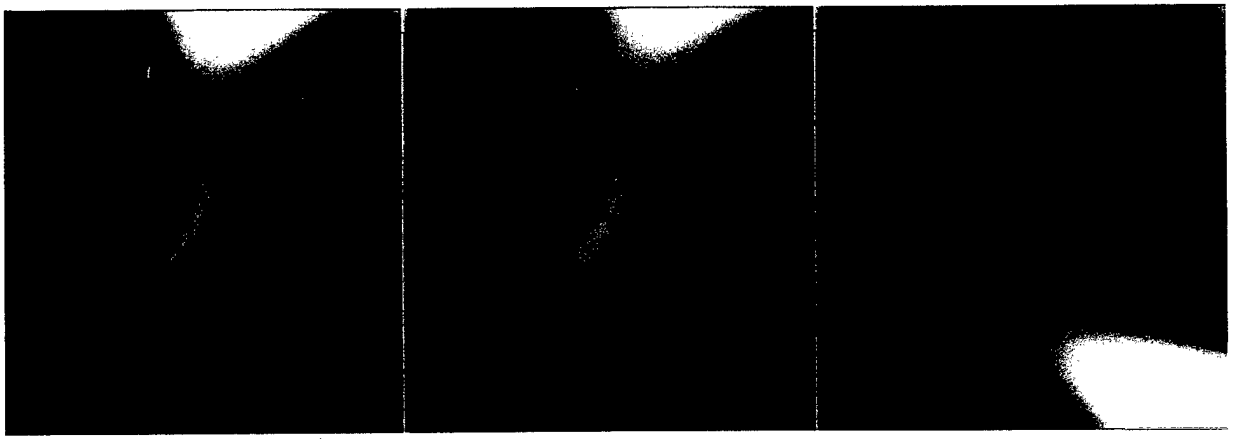


Figure 6. Dissection of Ethmoid Bulla

The approach for solid structures, such as the uncinate process, displaces rather than removes dissected vertices. When dissection occurs, patient model vertices move from inside the instrument's dissection volume to outside. The displaced vertices receive new positions, normals and colors appropriate to the dissected anatomy. A simple non-anatomical

geometric object constrains vertex displacement and defines vertex motion (Figure 7). Figure 8 shows dissection of the uncinate with a left-side back-biting forceps (surrounding anatomy has been removed for clarity). Vertices in the uncinate move in a direction that extends radially from the center of a sphere. The sphere's radius limits vertex displacement, ensuring that dissection causes no discontinuity between the uncinate and adjacent anatomical structures.

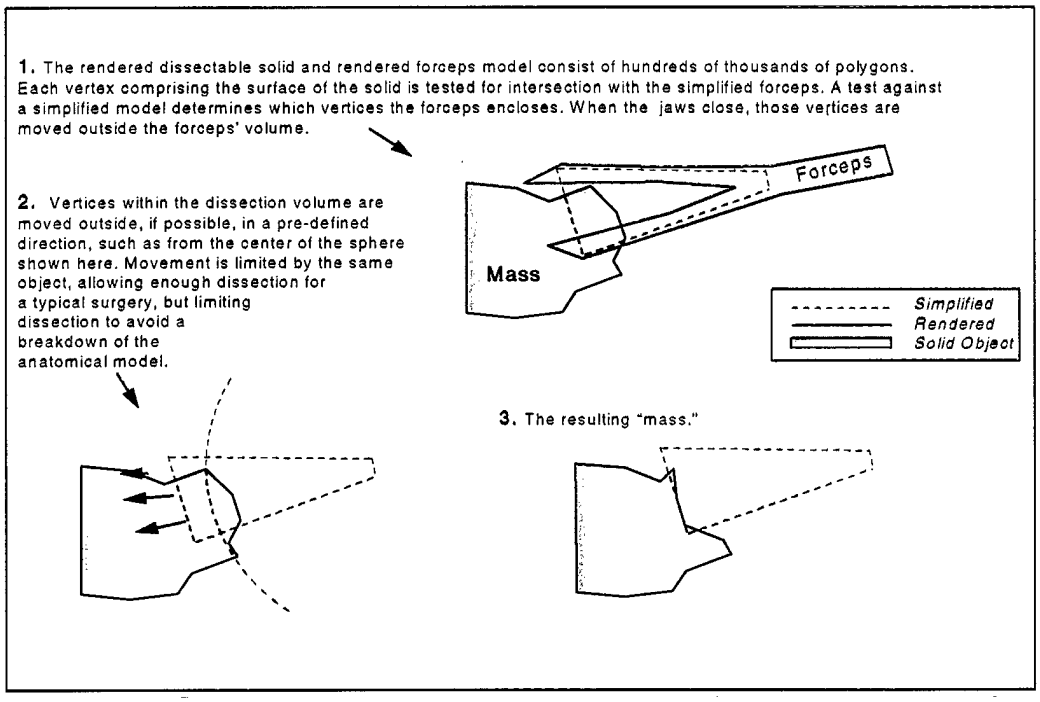


Figure 7. Tissue Mass Dissection

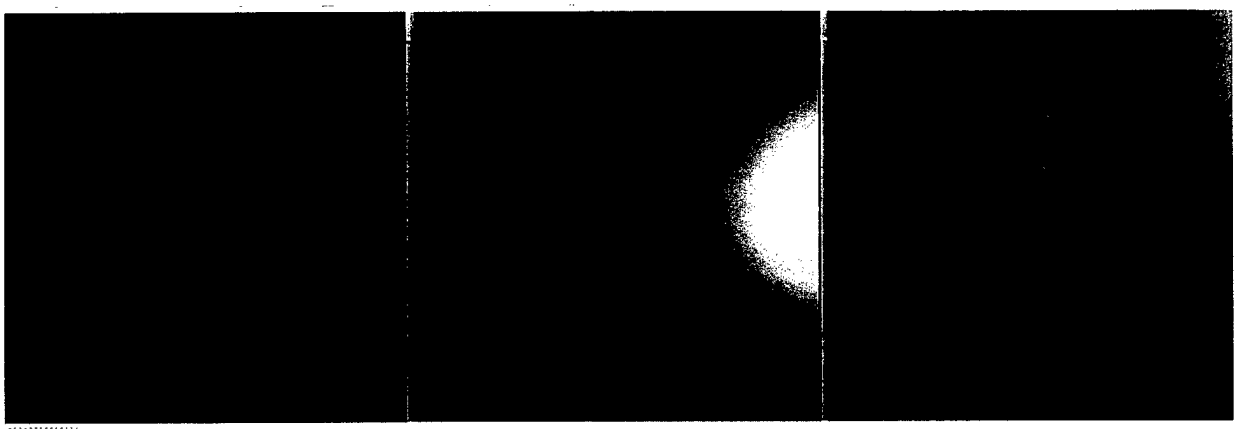


Figure 8. Uncinate Dissection

Incision with a knife or scissors is similar to dissection. For most anatomical structures, an incising volume is a simplified model that approximates the instrument's geometry.

However, in the case of the uncinate or turbinate, a plane separates vertices that connect to adjacent anatomical structures from those that do not connect. Incision of these structures removes vertices in a volume that starts as the tool dissection volume and extends away from the separation plane far enough to encompass the extent of the structure's tissue.

Because the sinus anatomy is rigid to good approximation, there is only a limited need for modeling tissue deformation. Medialization of the middle turbinate to gain access deeper into the sinuses is the only maneuver requiring deformation. The simulator employs a simple algorithm to displace vertices representing this fragile bony structure. A separation plane divides the turbinate's vertices into those that move and those that remain stationary, preserving the integrity of the overall patient model. Movement of each vertex is a function of its distance from the separation plane. Movable vertices farther from the plane undergo more displacement than those adjacent to the plane. The algorithm constrains turbinate movement to where the turbinate does not contact adjacent structures. A realistic finite-element approach would have been costly in computational resources and is not necessary for training. The simu-lator does not model surface depression via instrument palpation because of computational resource constraints and lack of training value.

Injection of a vaso-constrictor reduces bleeding, a required step in sinus surgery. The simulator employs recursive algorithms to find vertices inside the needle's injection volume, averaging their original color with blood red to simulate the puncture. Vertices, in a larger volume surrounding the needle's tip, mix with white to simulate the blanching. Figure 9 depicts an injection in progress.

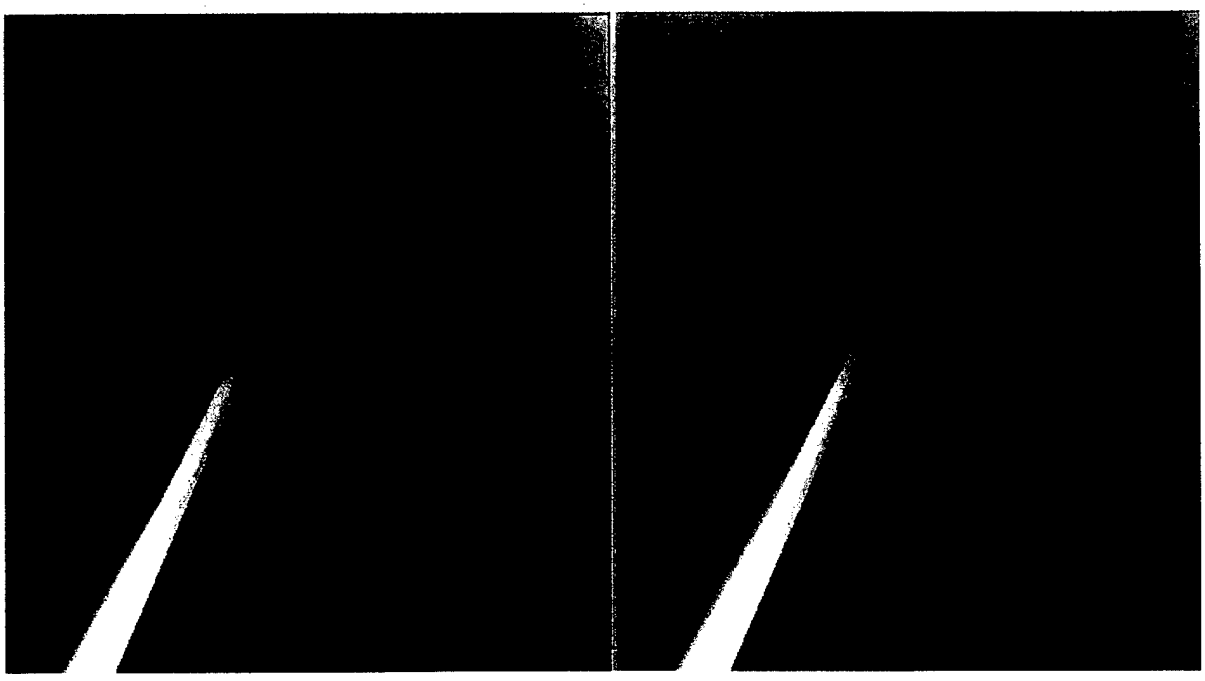


Figure 9. Injection of the Nasal Passage

The Simulator – Patient Model Development – Overview

The intricate anatomy of the human head and neck is a demanding region to master. A computer-generated surface that accurately represents the sinuses requires hundreds of thousands of polygons, stressing current technology. Texture, shading and sophisticated lighting that moves in real time with the eyepoint add to the complexity of rendering hardware. Light source motion precludes preprocessing of highlights so that the rendering pipeline must calculate them in real time.

The patient model development process that created a 3D sinus model for use in the simulator was influenced by two opposing goals:

a. Fidelity: The model must accurately represent the sinuses, providing a "realistic" training experience.
b. Efficiency: The simulation computer must be able to render the model in under 30 ms so that it responds quickly to student actions.

The National Library of Medicine (NLM) Visible Male data set formed the basis for deriving the simulator's patient models. A total of 1.7 GB of data, consisting of magnetic resonance (MR), CT, and color cryoslice photographs, comprise the record of the subject's head and neck.

NLM axial CT images were the source for the coronal CT images displayed in the simulator and also for the cube of CT densities used to determine the stiffness of contacted tissue. Processing of these forms of the patient model is trivial and discussed no further here.

The development tools and processes that create the renderable patient model underwent iterative refinement, improving both patient model fidelity and performance. These paragraphs focus on the three methods that comprise the renderable model development process:

- Segmentation
- Surface Extraction
- Surface Simplification

The Simulator – Patient Model Development – Segmentation

The set of NLM 2048 x 1216 x 24 bit cryoslice images was the source for reconstructing the patient topology. These images contain higher spatial resolution, 0.33 x 0.33 x 1.0 mm, than the CT or MR images.

The first step in the process used SGI's *frombin* utility to convert the cryoslice images from NLM format to SGI red, green, blue (RGB) format. Using SGI's *subimg* routine, investigators then cropped the original images to focus on the sinuses, reducing each image to a manageable 351 x 426 x 24 bits. Figure 10 depicts a cropped cryoslice image.

The subject's nose is at the bottom of the screen; the blue areas are hollow sinus cavities. After cropping the cryoslice images and discarding images above the frontal sinuses and below the palate, investigators still had 57 MB of source data to manage.

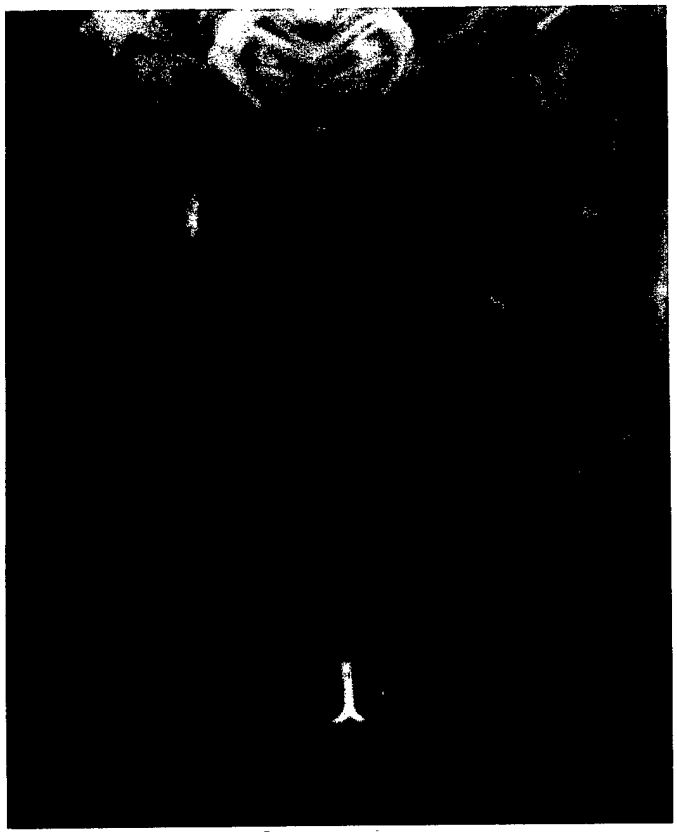


Figure 10. Cropped Cryoslice

Investigators encountered significant problems extracting surfaces from the NLM data. An apparent side effect of freezing, swollen nasal mucosa, obscures the normal anatomy of the osteomeatal complex. Also, the resolution was insufficient to capture the finer details in the sinuses.

Pathology in the right nasal passage complicated matters further. A large polyp exists beneath the middle turbinate. Additional polyps appear near the superior margin of the nasal cavity and inside the ethmoid air cells. Therefore, the subject's left side, and mid-line structures, such as the sphenoid sinus, became the basis for the patient model.

To perform image segmentation, investigators used a segmentation program written at The Ohio State University (OSU) consisting of neural networks using oscillators. This program, Graph - Locally Excitatory Globally Inhibitory Oscillator Network or G-LEGION (26-27). G-LEGION combines the functionality of neural networks with region growing. It groups pixels locally, using the difference between neighboring values.

As with all region-growing algorithms, G-LEGION tends to merge neighboring regions that have similar characteristics. Where merging occurred improperly, investigators bound the problem with a three-dimensional box and resegmented the bound volume using a new threshold, tailored to solve the specific problem.

The area of the skin just inferior to the root of the nose proved difficult because of noise in the surrounding fixing medium. G-LEGION had trouble defining a sharp boundary. Investigators again used restrictive thresholding to segment a smooth skin surface (Figure 11).

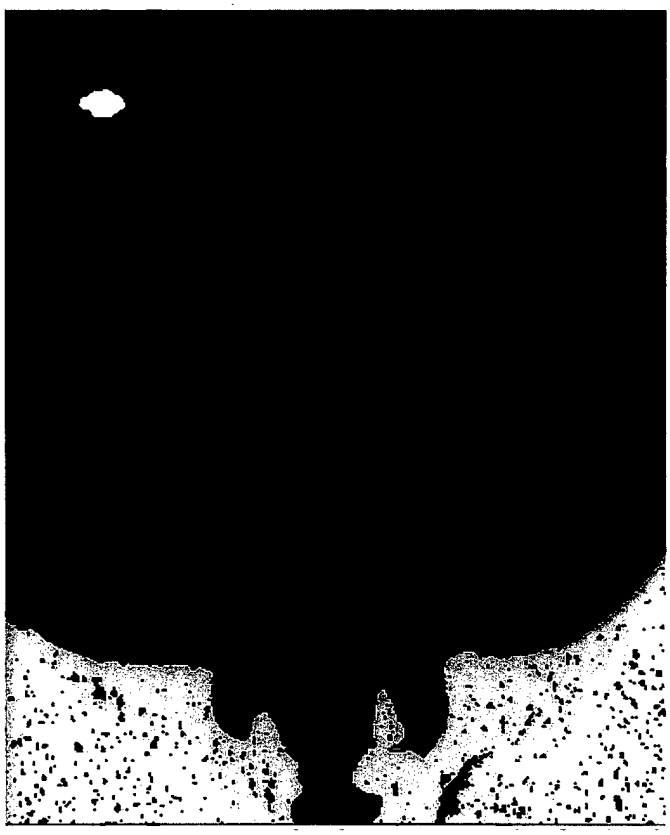


Figure 11. G-LEGION Results

G-LEGION results were promising. The algorithm performed well using data that contained noise and ill-defined boundaries. However, G-LEGION did not provide a finished product. The G-LEGION software left noise in the segmented image and failed to completely segment some regions. Also G-LEGION could not automatically correct problems with swollen tissues and lack of resolution in the data set. These required manual intervention.

G-LEGION creates segmentation masks which are images that have a unique color for each image segment. For example, in Figure 12, the middle turbinate is dark blue and the nasal airway is yellow. To enable manual refinement of the segmentation masks, investigators created Editmask using the SGI ImageVision Library. Investigators load original cryoslice files and tint them with Editmask, utilizing G-LEGION segmentation results. They are able to zoom into problem areas and page up and down through the slices. Editmask enables

segment mask editing through mouse-driven painting and erasing. Another feature, useful for removing noise, allows investigators to create and fill polygons.

Figure 12. Hand-Edited Segmentation Masks and Tinted Cryoslice Image

Limitations in the NLM resolution are apparent in several structures including the uncinate and the maxillary ostium. Therefore, investigators had to "improve" the data by adjusting the segmentation masks to create a more realistic depiction of the structures in the reconstructed topology.

Raw data
|
Convert to SGI RGB images
(frombin)
|
Crop images
(subimg)
|
Segment images
(G-LEGION)
|
Hand-edit segmentation masks
(Editmask)
|

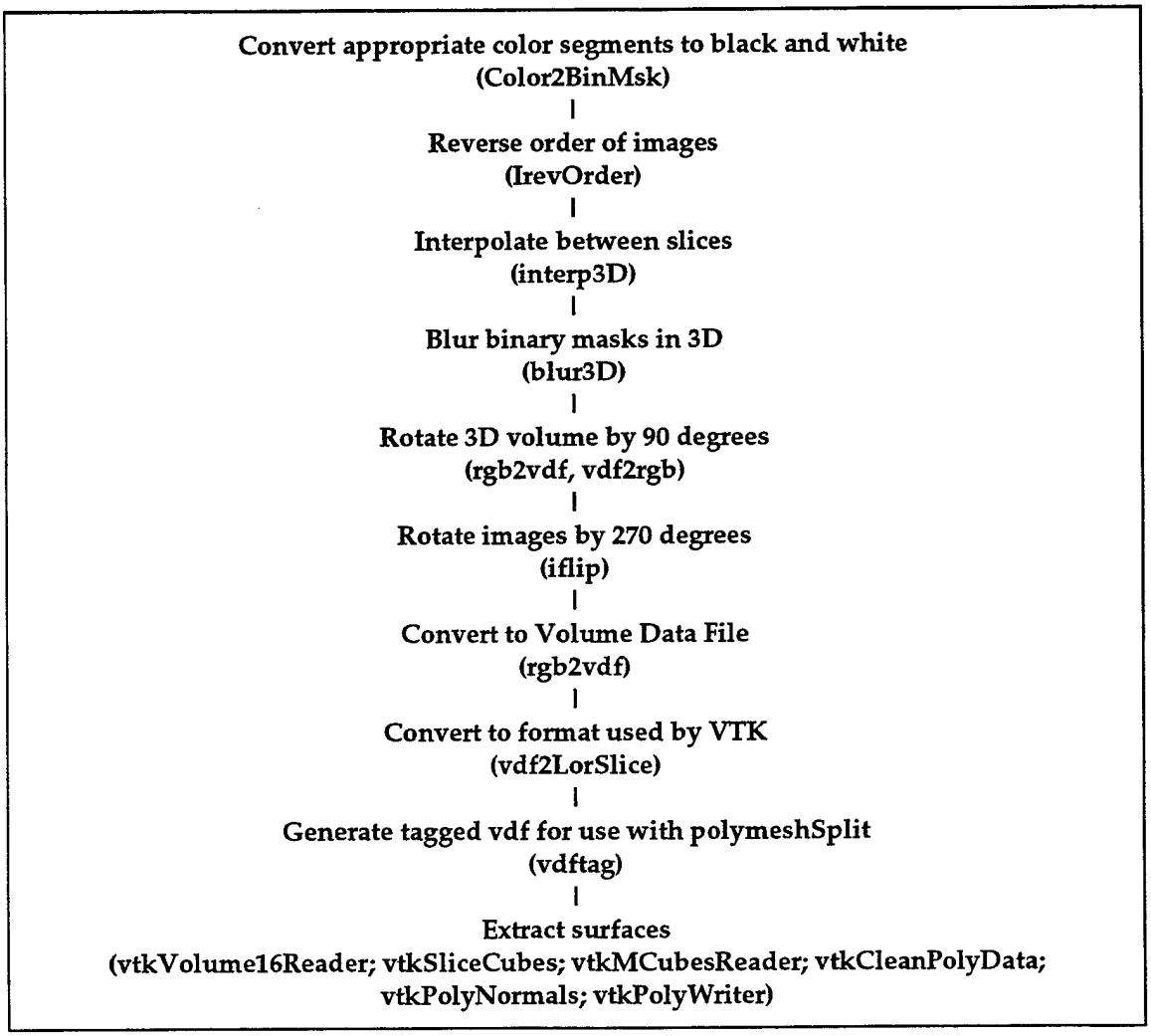
Segmentation Process Flow

The Simulator – Patient Model Development – Surface Extraction

For surface extraction, investigators downloaded the Visual Tool Kit (VTK) from General Electric's web site. This freeware provides a Marching Cubes (28) method to extract polygons from volumetric sets.

The first step in this process is to convert all segmentation masks to black and white (Color2BinMsk), where black is air and white is tissue. This allows generation of a single continuous surface that comprises all segments. Another investigator-developed tool, polymeshSplit, separates polygons into their appropriate segments.

Recall that the data resolution is 0.33 x 0.33 x 1.0 mm. The resolution is not identical for all axes, causing banding to appear in the resultant polygonal model. To address the problem, investigators added slices via interpolation so that the Marching Cubes software would have volumetric data with identical resolution in all axes. Investigators used SGI's ImageVision



Surface Extraction Process Flow

Library to develop interpolation software (interp3D). Interpolation occurs in one dimension using corresponding pixels in the user-specified number of neighboring images. Investigators developed two interpolation functions. One applies equal weight to all samples. The other uses a Lagrangian function that approximates a polynomial over the sample values. The Lagrangian filter delivers noticeably better results.

The Marching Cube algorithm computes normals using local variations in the surface, causing wild fluctuations. This approximation is unacceptable when the rendering pipeline uses normals for shading. Using the ImageVision Library, investigators developed 3D blurring software that inputs the volume of masks and blurs the data (blur3D). Investigators implemented a 3D box filter and Gaussian filter. To handle the edge of the volume, they reflected the images, extending the volume. Although not optimal, this approach provided useful results. The software uses a command line interface for easy insertion into the processing pipeline.

The Simulator – Patient Model Development – Surface Simplification

Investigators wrote the polymeshSplit algorithm to separate polygons into functional groups. The algorithm checks each vertex for inclusion into one or more patient segments. Some belong to adjacent segments. During simplification, the smoothing and decimation iterations rely on this information to maintain the integrity of the topology. No simplification occurs along the boundary between adjacent patient segments.

For surface simplification, investigators use the Laplacian smoothing software based on Taubin's work at IBM-Watson (29). This method reduces the high frequency in the geometry of the polygonal mesh. The technique suffers in that excessive smoothing removes smaller surfaces and desired details.

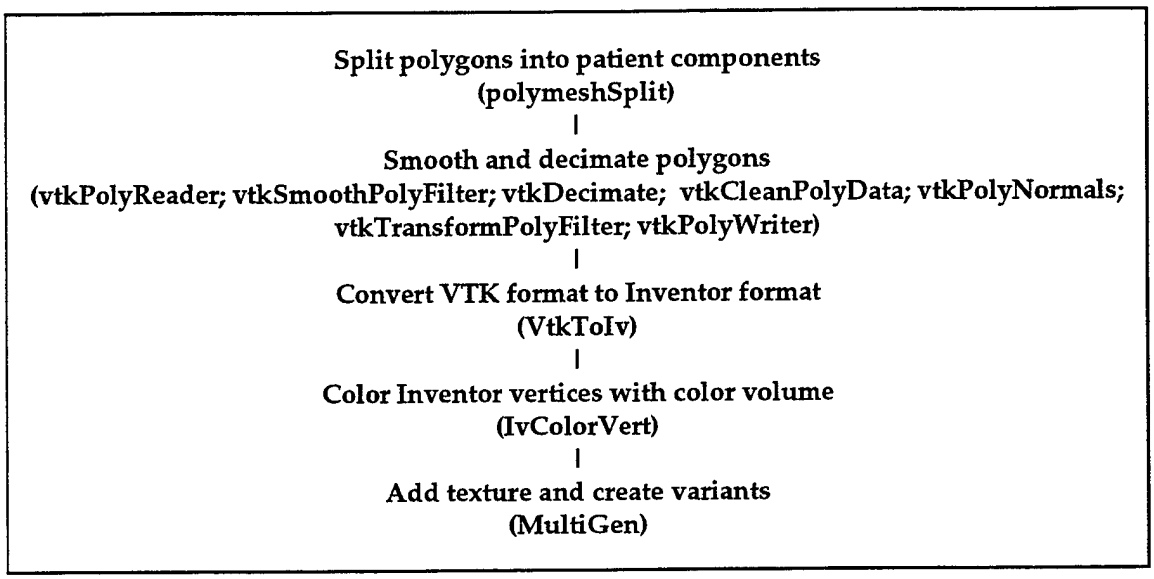
In addition, the VTK decimation software evaluates each vertex for local planarity. Upon meeting certain thresholds, it removes the vertex and modifies the local topology. This decreases the total number of polygons while preserving intricate surface details.

The vertex coloring program (IvColorVert) colors an Inventor file using a volume of color that overlays the space occupied by Inventor file polygons. Since real-time performance was a key objective of the process, investigators generated polygons at several levels of fidelity:

Low resolution	=	11680 triangles
Medium resolution	=	29401 triangles
High resolution	=	54650 triangles
Very high resolution	=	153987 triangles

High and very high resolution data sets contain more surface detail and richer color, but do not deliver real-time performance. Therefore, the simulator uses a combination of low and medium resolution components. Investigators partially overcame shortcomings in the lower-fidelity data by applying texture to the surface using a commercially available modeling tool, MultiGen. For texturing, the graphics hardware processes a gray-scale texture, modulating shaded colors at and between the vertices. This adds surface pattern detail between vertices.

MultiGen allowed investigators to contort various anatomical structures, creating pathological variants. For example, using MultiGen, investigators modified the standard middle turbinate to create both a paradoxical turbinate and a concha bullosa.



Surface Simplification Process Flow

The Simulator – Patient Models

The standard patient model consists of approximately 25,000 polygons. The model is a realistic representation of the skin, nasal passage, turbinates, ethmoid sinuses, maxillary sinuses, and the sphenoid sinuses. Segmentation of these anatomical structures is the first level of organization in the patient database. For example, the uncinate is in its own file. Each structure belongs to a software class that models its behavior under surgical interaction. Surgically relevant anatomical segments include the ethmoid cells, uncinate process, maxillary ostium, sphenoid ostium and middle turbinate. Segmentation also permits scoring and allows for easy substitution among the patient variants. Figure 13 shows the skin.

At load time, simulation software further organizes each patient model segment spatially. This allows the graphics rendering software to traverse only that subset of the database likely to be within the instantaneous view of the endoscope. The culling of the database greatly improves performance by reducing the number of polygons handled by the rendering pipeline.

The simulator uses pre-processed patient models in three forms. First, the instructor interface retrieves and displays coronal CT images stored in a generic, eight-bits-per-pixel, row-ordered format. Second, simulation software reads a lower resolution cube of CT images for determining stiffness of encountered tissue. Third, the rendering and surgical interaction software use the result of the patient model development process, which is a geometric representation of the anatomy in Open Inventor format. Vertices, surface normals, and texture coordinates comprise the geometric data used in the rendering process.

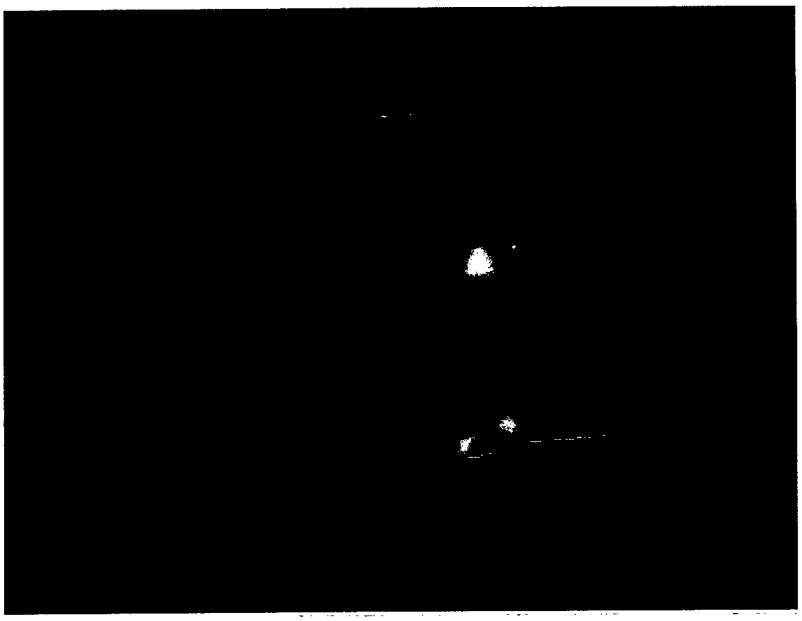


Figure 13. Skin Model

Along with the standard "healthy" patient, there are variants that enrich the student's training experience. To enhance military readiness, surgeons use the trauma model shown in Figure 14. The model contains a low-velocity projectile, such as a piece of shrapnel, that enters through the left cheek near the eye and lodges in the maxillary sinus cavity. A case performed by Dr. Gregory Wiet from OSU served as the real-world example on which to base this model. Robert Eisler's full report on trauma to the sinus area is included here as Appendix D. The figure shows the entrance wound and the bullet being removed by an up-biting forceps. Damage to various anatomical structures is visible in the endoscope. The surgeon can use the endoscope to traverse the shrapnel's path through the skin.

Figure 14. Trauma Model – Shrapnel Extraction

Variants to the standard and trauma models can exist alone or in combination. Among these are a deviated septum, concha bullosa, paradoxical turbinate and polyps. Surgical treatment on the simulator is possible for all but the deviated septum. The simulator contains reflected versions of all models to enable both left and right nostril training.

The Simulator – Virtual Instruments

The simulator provides a palate of 15 surgical instruments (Figure 15). Investigators used SGI's Interactive Three-Dimensional Modeler (I3DM) to develop the instrument models, the source data for which was actual instruments and images on videotape.

For each instrument, a Performer-loadable file specifies the visible geometry, emissive color, reflective color,specular highlight color, and shininess. A second file defines the simplified, non-rendered geometry for haptic and surgical interactions. Each instrument's software is an object derived from the base surgical instrument class, facilitating unique instrument behaviors.

To understand the need for these instruments, consider the following, typical procedure. After exploring the anatomy, the surgeon uses a straight needle to inject surfaces of the anatomy that are nearly perpendicular to the inserted instrument. Then, the surgeon bends the needle for injection of surfaces that are nearly parallel to the shaft of the instrument. The injected vaso-constrictor reduces bleeding. The surgeon then medializes the middle turbinate with the freer to gain access deeper into the sinuses. If the turbinate is pathological, the surgeon may dissect it with scissors. The uncinate process is dissected with a left or right side back-biting forceps (depending on which nostril), or a sickle knife. Blood, tissue, and bone fragments are removed with the suction instrument. Using straight or up-biting forceps, the surgeon removes other tissue and bone fragments and then punches through the ethmoid bulla, removing more tissue. The microdebrider is used to clean out the remainder of the ethmoid cells. Proceeding to the maxillary ostium, the surgeon uses a circular, left or right antrum punch to perform a maxillary antrostomy.

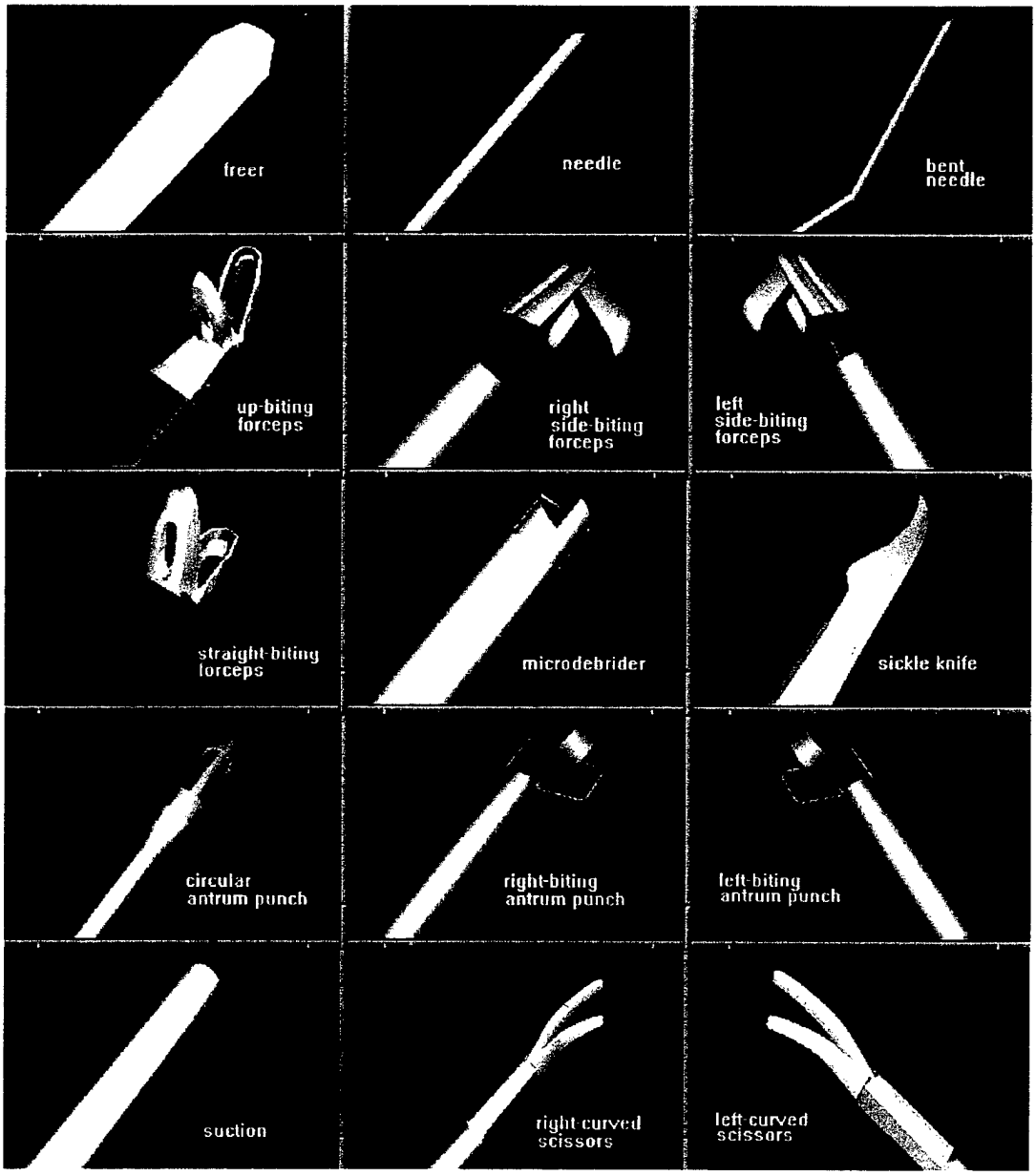


Figure 15. Instrument Palette

The Simulator – Computer-Assisted Instruction

One appealing aspect of computer simulation is the potential to educate students and automatically assess their performance. Novice, intermediate, and advanced training levels require unique training aids. The simulator has built-in aids for each level that guide and score student actions. At the advanced level, the student performs a limited anterior ethmoidectomy without prompting.

Among the simulator training aids are aligned successions of brightly colored hoops, forming paths through which the student must maneuver the endoscope for a training score. The paths guide the examination of the patient prior to surgical interaction with the patient anatomy. While paths for all training levels are identical, the novice level lacks the context of patient anatomy. Upon completion of the examination, targets in the form of bull's-eyes appear, prompting the student to begin the injection phase. At the end of the injection phase, a sequence of spherical masses provides novice-level dissection training, one mass for each of the dissecting instruments. When a marker is completely removed, the student receives a score of 100% for that marker. Scores are reduced if the action exceeds the recommended time.

Figure 16 shows the novice training environment through the endoscope. Red capsules with white caps provide rich motion and attitude cues.

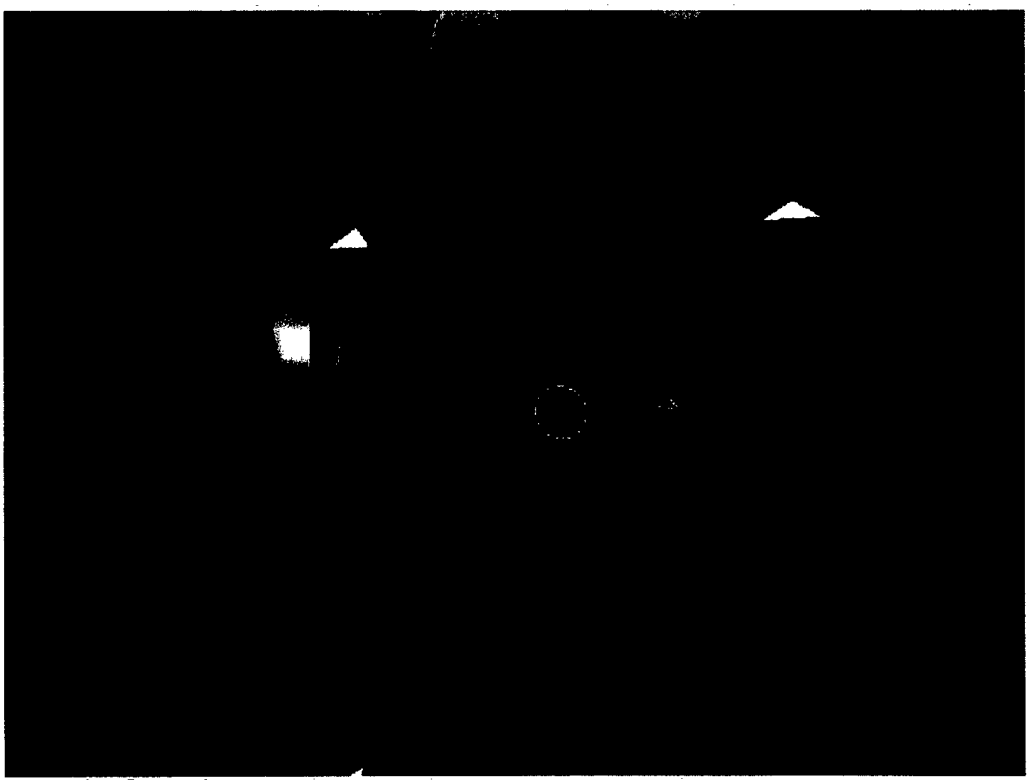


Figure 16. Novice Model

As shown in Figure 17, intermediate students interact with identical hoops and targets that now appear in the context of sinus anatomy. The dissection task at this level transitions from novice-level spherical masses to more realistic representations of patient anatomy. Labels appear near anatomical structures to help students identify dissectable components and provide landmarks. Dissection scores reflect the percentage of vertices removed from dissectable components.

Figure 17. Intermediate Model

Figure 18 depicts the advanced model. Advanced students see no hoops, although invisible hoops score their actions. No targets guide injection; rather, scores reflect student injection of appropriate sinus structures. The labels are invisible, but instructors may activate them if the student requires assistance. Advanced-level dissection is identical to intermediate level dissection.

Audible cues announce progress toward completion of the procedure and suggest the next course of action. As a student successfully negotiates each hoop, the simulator announces "Hoop," providing instantaneous positive feedback. Upon completing the examination, the student is advised by the simulator to "Begin injection." The simulator tracks progress through the injection with audible cues, such as, "Middle turbinate injected 25%." As he successfully completes the injection, the student hears "Begin dissection." Announcements of progress continue during dissection of the various anatomical features, e.g., "Uncinate dissected 25%."

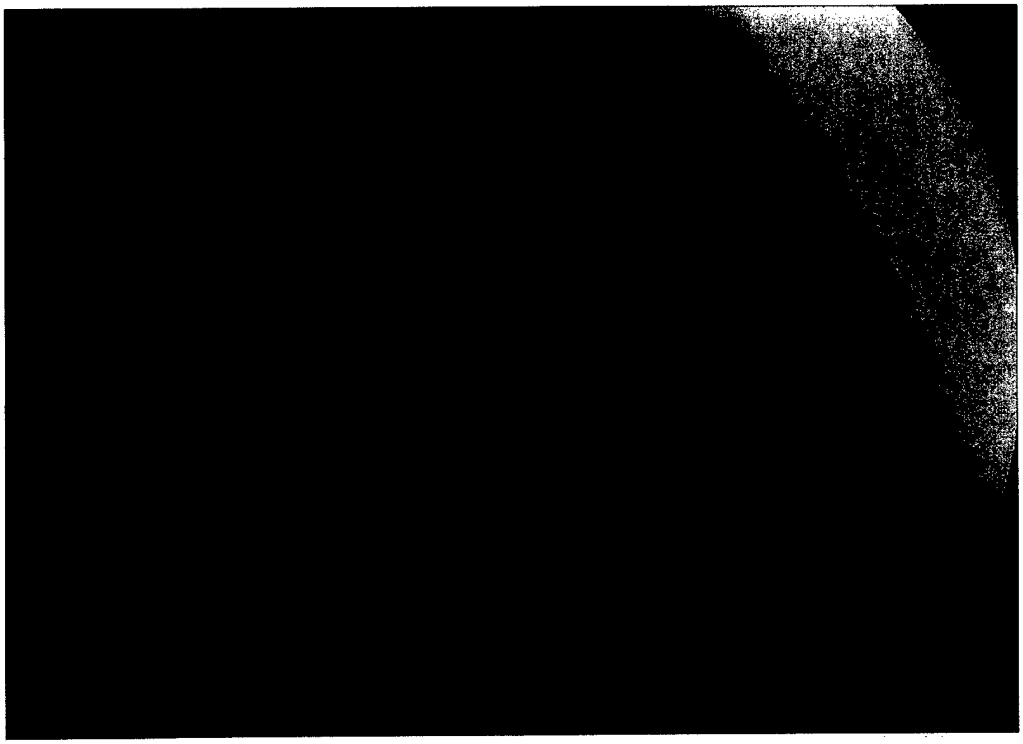


Figure 18. Advanced Model

The simulator records student inputs frame-by-frame, precisely auditing student actions. This stored data is useful for student evaluations, as described later in this report. The simulator features a playback capability in which it ignores haptic system inputs and plays back the previously recorded student and instructor actions to recreate the procedure. Playing back expert actions conveniently demonstrates surgical procedures for student training prior to simulator use.

At the time the proposal was written, the development team intended to develop a stand-alone, interactive tutorial in a question-and-answer format. Dr. Edmond compiled 150 questions to include in the course; however, he chose to abandon the development of the tutorial in favor of the simulator-based, computer-aided instruction described above.

EVALUATION

The following sections contain significant portions of the formal simulator evaluation; Appendix E contains the complete evaluation. The evaluation was performed by the Human Interface Laboratory completely independently of the development effort. For this project, evaluations were of two general types:

- "Formative" evaluation, which provided design specification input to the development team
- "Summative" evaluation, which assessed the success of that effort by formally analyzing the system's effectiveness

Evaluation – Formative

Throughout the simulator's development, the evaluation team worked in close collaboration with Dr. Charles Edmond to perform the formative evaluation and make design recommendations to the development team.

A considerable amount of effort was involved in establishing a "curriculum wrapper" during the development phase. Investigators initially envisioned the simulator embedded within a multimedia training system that would provide a meaningful context and set the protocol for the trainee.

The development team elected instead to integrate relevant aspects of the emerging ENT curriculum into the simulator itself and to postpone further efforts to develop a total curriculum "package." The reasons for this included:

- Development of a full-blown ESS curriculum was beyond the scope of this phase of the project.
- It became apparent that a staged protocol approach was necessary to make the simulator effective in a training context.
- Useful techniques emerged, such as the use of navigation hoops and injection targets, that could be integrated relatively easily.

Evaluation – Summative

The primary goals of this phase of the evaluation effort were to validate the simulator's utility as an ESS training environment, assess its usability, and provide feedback to the development team.

Evaluation – Subjects

Investigators solicited subjects from three groups: non-physicians, non-ENT physicians, and ENT staff and residents. Investigators these subjects to establish a baseline and asymptote for the evaluation of the efficacy of the simulator. The non-ENT groups allowed investigators to "shake down" the system and research protocols without utilizing valuable

ENT resident subjects. They also provided baseline scores for untrained/unfamiliar subjects. The non-ENT physician group also provided investigators with valuable input about the extensibility of the simulator to non-ENT applications.

Twelve volunteers from the University of Washington College of Engineering comprised the non-physician group. Subjects ranged in age from 23 to 54 and included graduate students, professional staff and faculty. All had some experience with simulation and virtual reality. None had previously used an endoscope or attended medical school.

The non-ENT physician group consisted of eight University of Washington physicians from specialties other than otolaryngology. This group provided extensive feedback on the simulator design and utility for other medical and surgical tasks, and included three videoendoscopic surgeons, two radiologists, one neurosurgeon, one cardiologist, and one anesthesiologist. Four of these subjects also provided investigators with complete trial performance data.

The ENT group comprised twelve staff and resident ENTs from MAMC: four staff, three second-year, one third-year, two fourth-year and two fifth-year residents. Note that in this report, investigators combined the single third-year resident with the two fourth-year residents to ensure confidentiality.

Evaluation – Performance Criteria

The scoring algorithm for Version 1.2 of the simulator takes into consideration both accuracy and time. The endoscopic surgical procedure comprises navigation, injection and dissection tasks. The overall trial score is:

overall score = (navigation score + injection score + dissection score)/3

where task scores are:

*task score = accuracy*optimal time/completed time*

Evaluation Results – Non-Physicians

Although not the target domain audience for this simulator, the non-physician group provided an opportunity to look at the difficulty of the simulator for domain-naive users and to further work out requirements for instructional presentation, proctoring, and pacing of the "curriculum." Since the novice model did not require detailed knowledge of the surgical procedure or interaction with the complex paranasal sinus anatomy, it was felt that this group should be able to complete the trials.

The inherent difficulty of the task for inexperienced users is evidenced by attrition and initial trial scores. Indeed, complete trial data are available for only nine of the 12 subjects in this group. Of the three lost to attrition, one terminated the session due to disorientation and discomfort, and two were unable to complete even the navigation task during the time period available for testing. They were not able to acquire the basic skill necessary to control the positioning of the virtual endoscope.

Of the nine remaining subjects in this group, five had considerable experience with videogames and three with commercial flight simulators. Thus, the trial scores for this group probably represents the high end of non-physician users and should not be taken as a sample from the general non-physician population.

Despite attrition of the low-end performers and the unusual prior experience of the remaining subjects, the non-physician group performed significantly worse than the ENT group on their initial trials. Unpaired students' t comparisons with the ENT group revealed significantly lower overall trial scores for novice (non-physician mean = 45.9, ENT mean = 65.1, $t = 2.87$, $p = .0098$) and intermediate-level training (non-physician mean = 53.7, ENT mean = 76.7, $t = 3.53$, $p = .0041$).

Six of the 12 subjects in the non-physician group had complete trial scores for at least two novice trials. Students' t comparisons of their first and second novice trials showed that their second trial resulted in significantly higher trial scores (trial 1 mean = 46.7, trial 2 mean = 69.5, $t = 2.33$, $p = .0423$).

Evaluation Results – Non-ENT Physicians

The primary objectives of the non-ENT physician evaluations were to provide a medically trained comparison and "shakedown" group and to explore the perspectives of other medical specialties regarding potential applications for this sort of simulation training. In particular, investigators were interested in applications which might make use of the integrated approach and specific components incorporated into the Madigan ESS simulator.

Novice performance measures for the non-ENT physician group were very similar to the those for the experienced ENT group. While there were no statistically significant differences between these two groups, the mean differences for all of the performance measures were in the expected direction. This finding may be due to the considerably broad prior medical and interface experience for subjects in this group.

Three of the non-ENT physician subjects also tried the intermediate model. Comparison of the non-ENT physicians with the ENTs on their first trial on the intermediate model reveals an interesting finding. While there was no significant difference between the groups in overall score and trial time, the non-ENTs did considerably better than the ENTs on the dissection subtask (non-ENT mean = 84.0, ENT mean = 63.1, $t = 2.439$, $p = .0312$). Investigators expected that the ENT group would be superior to all other groups on this task.

Perhaps the greatest mitigating factor is the extensive experience that two of these four subjects had acquired as videoendoscopic surgeons. Their speciality gives them considerably more endocscopic experience than ENT physicians generally aquire. General videoendo-scopic procedures are more challenging from a psychomotor perspective. In addition to navigation, injection and dissection, their procedures may require retracting, cautery, cutting, suturing and true dissection, with the reflection of tissues away from the area of interest. Further, they perform these tasks in a more bi-dexterous fashion; the ENT surgeon uses both hands, but usually one at a time. Finally, the videoendoscopic surgeon's

psychomotor abilities may be challenged more during their procedures, because the endoscope and instruments are usually not coaxial.

Evaluation Results – ENTs

Simulator performance measures were acquired on 53 separate trials for the 12 ENT subjects between May and August of 1997. The number of trials acquired for each subject ranged from 2 to 12, with all subjects minimally experiencing both the novice and the intermediate model.

To examine the degree to which prior OR experience might contribute to these initial score differences, investigators calculated the Pearson product-moment correlation coefficients ("r") across the primary performance measures (trial time and trial score) and the primary experience measures (age, years of ESS training, and approximate number of actual ESS procedures performed). A matrix of these correlations appears in Table 1 (critical r = .6021 for probability $p < .05$, degrees of freedom df = 9).

As can be seen, the best predictor of novice trial time from among the surgical experience measures is the number of actual ESS cases performed (r = -.652), with trial time decreasing significantly with surgical experience. For trial score, the best experiential predictor is again the number of ESS cases performed (r = .526). This finding suggests that the simulator provides a valid reflection of the skills acquired in ESS procedures.

Table 1. Correlation matrix showing relationships among ESS experience measures and overall performance measures on novice model for 12 ENT subjects.

	Score	ESS perf	Years Tr	Age	Trialtime
Score	1				
ESS performed	.526	1			
Years training	.38	.923	1		
Age	.236	.662	.713	1	
Trialtime	-.966	-.652	-.514	-.33	1

Note: 1 case deleted with missing values

Figure 19 shows the breakdown of first-time novice (abstract) model scores for this group. The linear relationship between overall novice trial score and year of residency is apparent from this mapping. It is interesting to note that the R5 residents appear to have higher scores on the novice model than do the experienced ENT staff subjects. This could be due a number of factors, including the relatively high number of procedures being performed routinely by the R5s.

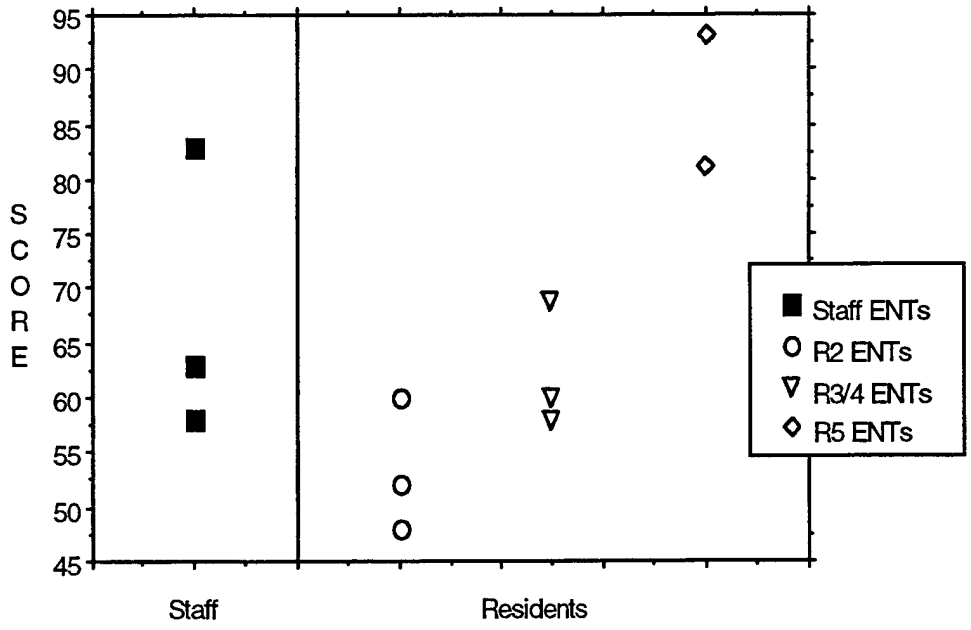


Figure 19. Overall Scores for First Trial on Novice Model

Although investigators expected a positive relationship between ESS experience and novice model performance, they anticipated that operating room experience would be even more predictive of performance at the intermediate level, when the sinus anatomy serves as the model. A matrix of these correlations appears in Table 2 (critical r = .6319 for $p < .05$, df 8). The initial performance on the intermediate model is positively correlated with prior ESS experience, but the relationship is not as strong as expected. This may relate to the training effect provided by the simulator in the novice model.

Table 2. Correlation matrix showing relationships among ESS experience measures and overall performance measures on intermediate model for 12 ENT subjects.

	Score	ESS perf	Years Tr	Age	Trialtime
Score	1				
ESS Performed	.555	1			
Years Training	.356	.931	1		
Age	.581	.667	.68	1	
Trialtime	-.795	-.144	-.014	-.475	1

Note: 1 case deleted with missing values.

As shown in Figure 20, scores on the initial intermediate trial generally improved with year of residency.

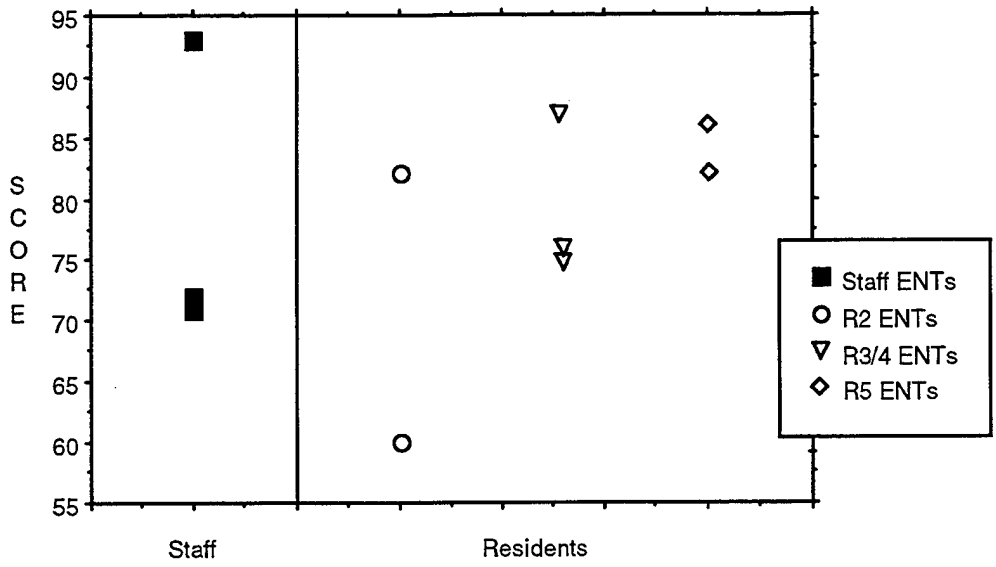


Figure 20. Overall Scores for First Trial on Intermediate Model for ENT Staff

While intermediate trial times for the ENT staff might be expected to be lower than those for the residents, their real-world experience with the procedure may actually make them more cautious, as noted above. The experienced sinus surgeon knows, for example, that if one traumatizes the septum or middle turbinate during the navigation phase, it will cause bleeding that will affect the rest of the surgical procedure.

Figure 21. Overall Times for First Trial on Intermediate Model for ENT Staff

Figure 22 shows the overall scores for the first advanced trial by subjects in the ENT group. Note that two of the staff subjects did not attempt the advanced model.

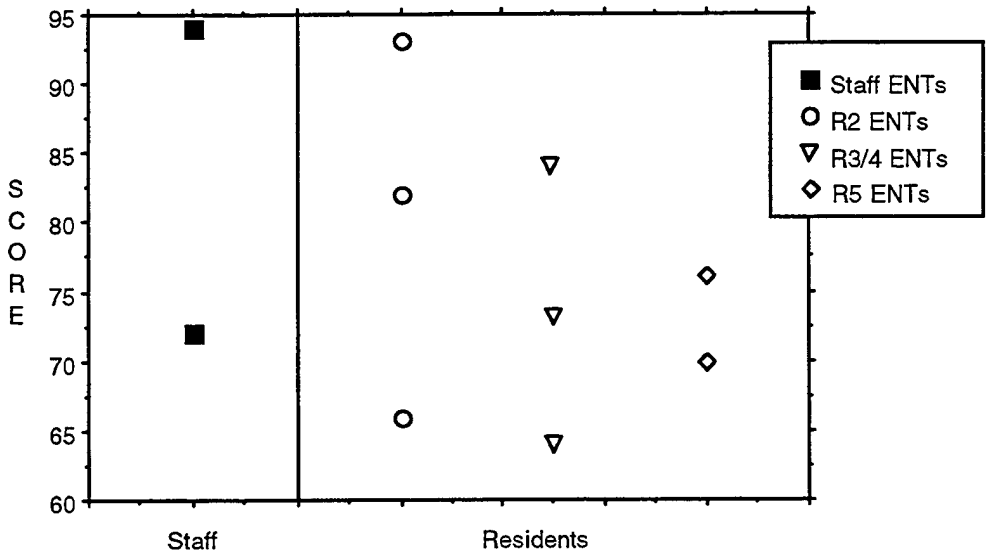


Figure 22. Overall Trial Scores for First Trial on Advanced Model for ENT Staff

Surprisingly, initial performance on the advanced model revealed a tendency for the more senior residents to perform at about the same speed as the staff ENT subjects, but with slightly lower overall scores. This may reflect the ability of the more experienced surgeons to perform maneuvers with a higher degree of accuracy. Also, since there is no strong correlation between initial performance at the advanced level and experience, one may

Figure 23. Injection Scores for First Trial on Advanced Model for ENT Staff

conclude that the novice and intermediate level experience provided its own training effect. In fact, the two highest resident scores were registered by subjects who had received additional novice and intermediate-level training.

While overall time and score for staff ENTs did not appear to differ uniformly from the resident times and scores on initial advanced model trials, their performance on the *injection* subtask appeared to be superior to the resident group (Figure 23). Similarly contrasting performance was not seen for the navigation and dissection subtasks.

Although navigation and dissection may vary with individual case and priorities, the data suggest that injection efficiency may be a hallmark of the experienced sinus surgeon. This finding should be followed up and verified in future evaluation studies.

Evaluation Results – Asymptotic Performance

While extensive learning curve data are not available, repeated measures on the steady-state system are available for our two primary evaluation proctors, an ESS surgeon and an engineering student. These two subjects each tested the simulator in various degrees of development 30-40 times over a 6 to 8 month period. Their later scores may provide an estimate of asymptotic performance on the simulator.

Figure 24 shows simulator performance scores for the last 11 trials by the experienced ENT proctor and the engineering student. These findings suggest that extensive experience with the simulator may afford a non-ENT subject performance values which are comparable with an experienced ENT proctor. Assuming validation of findings discussed above, this bodes well for the training effectiveness of the simulator.

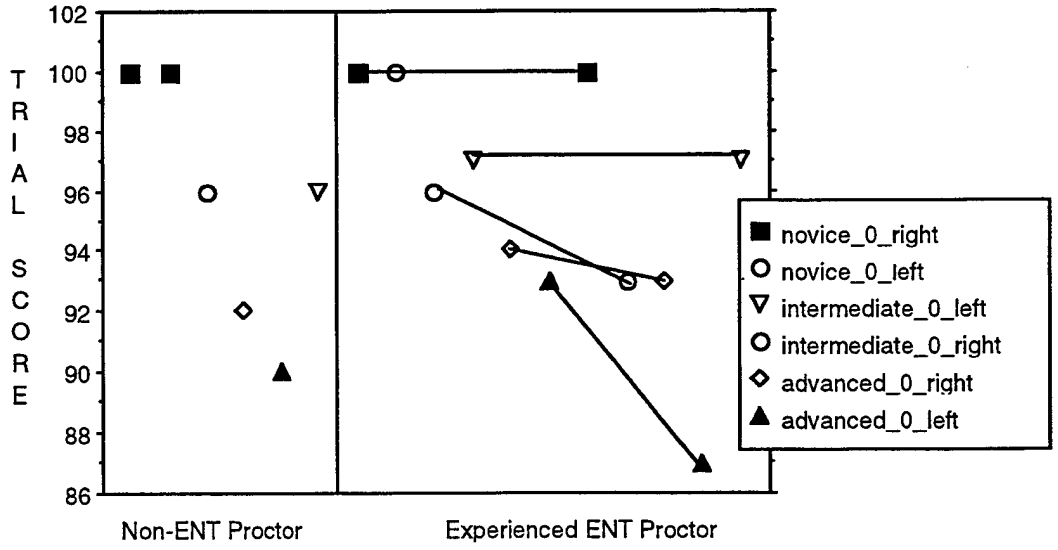


Figure 24. Comparison of Asymptotic Trial Scores on Each Model for Non-ENT Proctor and Experienced ENT Proctor

Evaluation – Optimal Path Analysis

Another approach for evaluating user performance is to look at the paths of the virtual tools over the course of a procedure. Figures 25, 26, and 27 show the performance paths of three individuals: a non-physician, a second-year resident, and a fifth-year resident, respectively. Each color in the figure represents an individual surgical tool used to dissect a small abstract sphere. In these tracings, the control shown in the color tracings is indicative of the precision and accuracy of the subject in manipulating the tool's position. (The dark blue lines should be disregarded, because they trace multiple scattered targets.)

The tracings of the non-physician are depicted in Figure 25. Figure 26 shows the tracings of a second-year resident. Notice that the colors show smaller, tighter movements. Cleary this subject performed better than the non-physician. Figure 27 shows the performance of a fifth-year ENT resident, indicating even better accuracy and precision.

In addition to drawing the paths for visual analysis, investigators calculated a set of objective scores based on the tool path data. The measure is calculated for each sphere as

*sphere path score = total frames * mean tool deviation from centroid / 1000*

Note that the lower the score, the better the performance. First-order correlation between the path measure and the original simulator score correlates with a value of -.798 (critical r = .4060 for $p < .05$, df 22). This further validates the scoring algorithm.

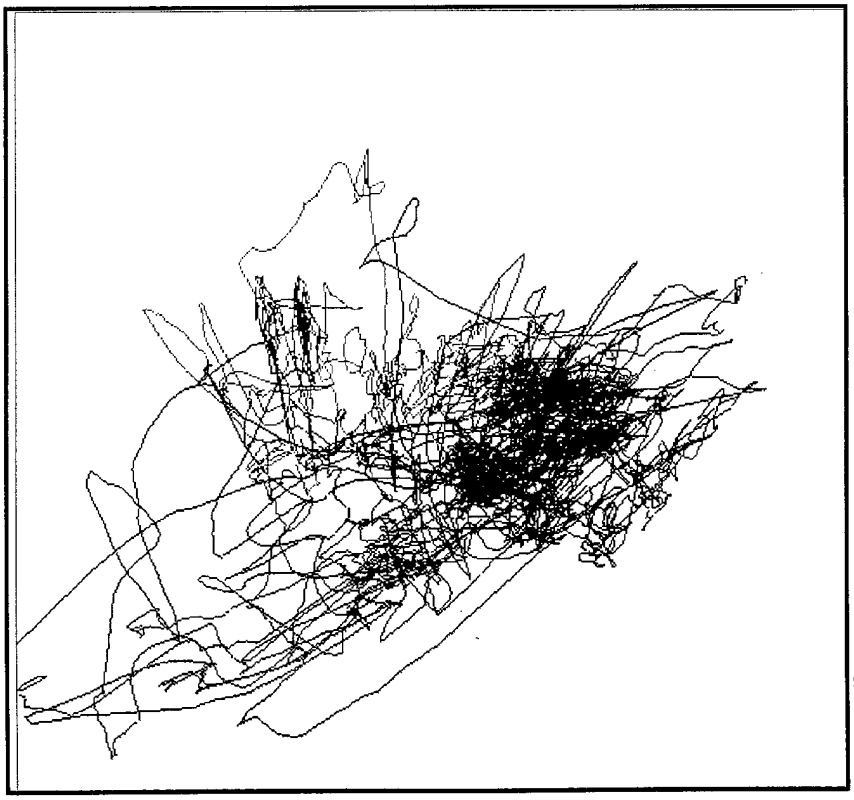


Figure 25. Simulated Dissection Task Performed by Non-Physician

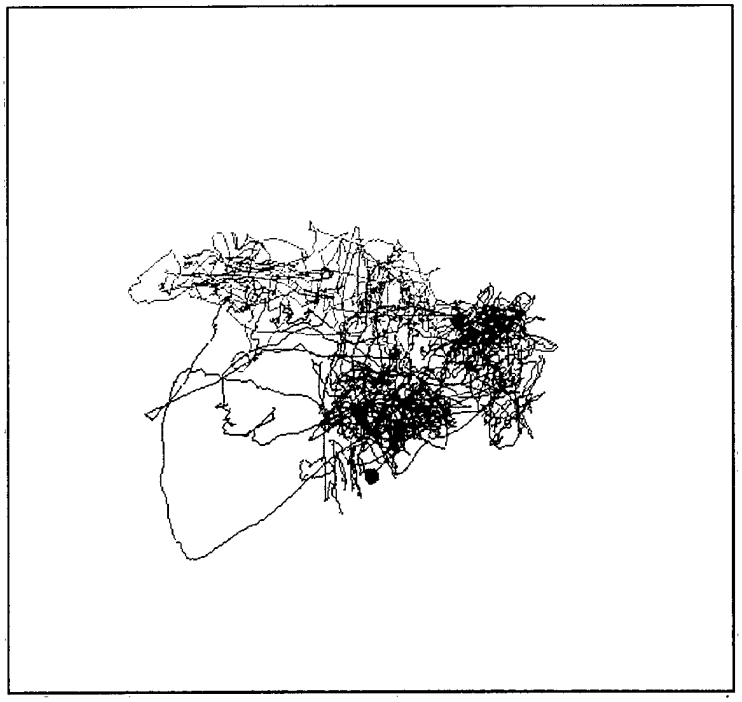


Figure 26. Simulated Dissection Task Performed by Second-Year Resident

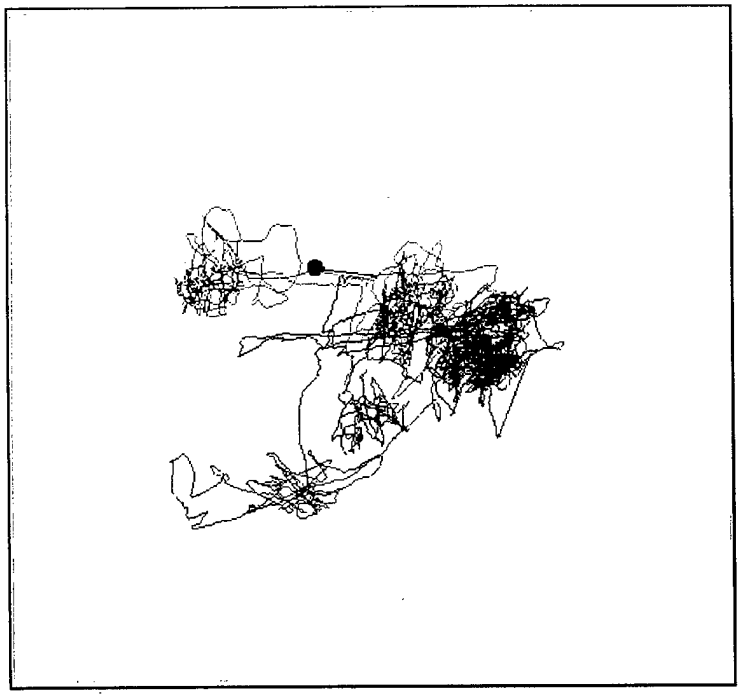


Figure 27. Simulated Dissection Task Performed by Fifth-Year Resident

RECOMMENDATIONS

Several areas in this ESS simulation project are recommended for further effort: patient model enhancements, hardware upgrades, software revisions, haptic refinements, and training effectiveness evaluations.

Patient Model Enhancements

The patient model should be refined. Model enhancements should revolve around increasing the number of polygons to take advantage of newer hardware and segmenting additional features. New anatomical features would include the frontal sinus, frontal recess, skull base, pituitary gland, and normal and pathological variations. A larger library of patient models would allow an instructor to select and create custom models to increase student familiarity with a wide range of conditions. These additions would also allow procedures for sister services that perform endoscopic techniques in the nose, such as an ophthalmological dacrocystorhinostomy or a neurosurgical endoscopic hypophysectomy.

Hardware Upgrades

As the patient model becomes more complex, the computational problem grows. Investigators made significant reductions in polygon counts to meet real-time performance requirements. The computational limitation resulted in less visual realism and perceivable latency when operating in the anatomically dense areas of surgical dissection. The acquisition of a more powerful computer would render more complex patient models without sacrificing real-time performance.

Software Revisions

Model enhancements and hardware upgrades require software modifications to support them. Additionally, clinicians desire an interactive training tool to aid student instruction by viewing the 3-D patient model in a perspective that is not available in the real world. Further software modifications will accommodate anticipated recommendations as the simulator undergoes field tests.

Haptic Refinements

Future work includes enhancing haptic system fidelity. This cooperative agreement did not allow sufficient time to explore the more challenging aspects of force feedback. The development team should weigh the cost of technologically immature haptic refinements over more perceptible gains in the other areas previously mentioned. At the end of this contract, investigators engineered changes to the haptic system to improve its reliability. There is, as yet, no data to judge the effectiveness.

Evaluations

Simulators have not yet proven themselves to increase readiness with respect to basic surgical skills. Future work has to begin to explore the impact of experience with the simulator on actual operating room performance. Investigators must gather the data necessary to evaluate training effectiveness.

Other

Future work will also consist of monitoring advances made by associate and peer investigators in areas of soft tissue deformation, volumetric rendering, finite element modeling, force feedback and embedded intelligence. Surgical simulation is emerging from its infancy, and its fulfillment will occur only through continued support from the visionaries, research scientists, and clinicians.

CONCLUSIONS

This cooperative agreement enabled the development of a state-of-the-art training device for endoscopic sinus surgeons. The ESS simulator takes medical simulation a major step forward in its evolution. Aside from its technical accomplishments, the integration of a well thought-out curricular framework allows it to take advantage of virtual reality without sacrificing the benefits of more traditional computer-aided instruction. Preliminary simulator evaluation results support the notion that recent gains in virtual reality technology enable real surgical skills and procedure awareness training.

The validity of the simulator for the ESS domain is suggested by a number of findings:

- ENT subjects performed significantly better than non-physician subjects on both the novice (abstract) and intermediate (anatomical with aids) models.
- Initial performance on the novice model correlates with residency level and degree of prior ESS experience.
- Patterns of difficulty for asymptotic performance on the simulator seem to match the typical pattern of subtask difficulty in the operating room.
- Subject ratings of the realism of the virtual anatomical model were consistently high on the post-session questionnaire and in open-ended comments.
- Post-training questionnaire responses confirm that the ENT subjects perceived the simulator as valid and useful for ESS training.

Our responses to questions put forth as the purpose of this cooperative agreement follow:

a. *Can surgical simulation enhance the comprehension and performance of minimally invasive surgical procedures?*

   Preliminary data indicates that the simulator can enhance comprehension and performance of endoscopic sinus surgery. However, this data is indirect. Continuation of studies started with this cooperative agreement will yield more direct measurements.

b. *Are objective performances of simulated surgeries useful in the evaluation of surgical competence?*

   While the evaluation suggests that the simulator objectively measures surgical skills such as speed, precision, dexterity, and spatial perception, there are other aspects of surgical competence such as cognitive ability, observations, deductions, and actions that require further study. Continuation of studies started with this cooperative agreement will yield more definitive results.

c. *What levels of visual complexity and tactile response are necessary to achieve enhanced training?*

   The evaluation suggests that the simulator is valid for the ESS domain. It appears that training takes place using the level of visual complexity and tactile response in version 1.2 of the simulation. The current revision, 1.3, incorporates substantial improvements in tactile response that should provide even better training.

d. *Can the above objectives be achieved at an acceptable cost?*

Lockheed Martin configured and demonstrated a low-price version of the simulator. Initial marketing inquiries show the price of that configuration to be acceptable to many in the medical community.

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APPENDIX A

RELATED PUBLICATIONS

and PRESENTATIONS

Related Publications

Edmond C, Billinghurst M, *Simulation: The Substitute Teacher,* Medical Simulation and Training, Volume 1, Issue 1, Summer 1996.

Edmond CV, Heskamp D, Sluis D, Stredney D, Sessanna D, Wiet G, Yagel R, Weghorst S, Oppenheimer P, Miller J, Levin M, and L Rosenberg, *ENT Endoscopic Surgical Training Simulator,* Medicine Meets Virtual Reality, K.S. Morgan et al. (Eds.), OIOS Press, Amsterdam, 1997, p. 518 - 528.

Sluis D, *Simulation and Surgical Training,* Medical Simulation and Training, Volume 1, Issue 2 Fall/Winter 1996.

Edmond CV, Sluis, D. *ENT Surgical Simulation Project.* Proceedings of the National Forum: Military Telemedicine On-Line Today Research, Practice, and Opportunities, IEEE 1996.

Edmond C, *Otolaryngology Training and Surgical Simulation.* Otolaryngology Head and Neck Surgery, Volume 115 No. 2., p. 135, 1996.

Edmond CV, Sluis D, *ENT Surgical Simulation Project.* Proceeding of the National Forum: Military Telemedicine On-Line Today Research, Practice, and Opportunities, IEEE 1996.

Billinghurst M, Savage J, Oppenheimer P, Edmond C, Health Care in the Information Age, Chapter 65. *The Expert Surgical Assistant: An Intelligent Virtual Environment with Multimodal Input,* p. 590-607, 1996.

Edmond, C and Billinghurst M, *Expert Systems in Otolaryngology.* Otolaryngology Head and Neck Surgery, Volume 115, No. 2, p. 135, 1996.

Related Presentations

Sluis D, *An ENT Endoscopic Surgical Training Simulator; Works in Progress,* Medical Technology Education Conference 7-11 July 1996, Orlando FL.

Edmond CV, *ENT Endoscopic Surgical Training Simulator,* Medicine Meets Virtual Reality, January 1997, San Diego.

Wiet GJ, MD, *The Simulation of Functional Endoscopic Sinus Surgery,* The William H. Saunder Lectureship, The Ohio State University Medical Center, June 1996.

Edmond C, "ENT Surgical Simulator" Presented to Medical Research and Material Command, Ft. Detrick, MD, Jan 27, 1995.

Edmond C, "Surgical Simulation, National Forum: Military Telemedicine On-Line Today Research, Practice, and Opportunities," McLean, VA, March 1995.

Edmond C, "New Horizons: Virtual Reality in Head and Neck Trauma Management," Presented at the 1st Annual Trauma Symposium, San Antonio, TX, June 13-15, 1995.

Edmond C, "Expert Surgical Assistant: An Intelligent Virtual Environment with Multimodal Input," Presented at Medicine Meets Virtual Reality: 4, San Diego, CA, January 17-20, 1996.

Edmond C, "ENT Surgical Simulator" Sinus and Allergy Update - Tetons, Jackson Hole, WY, June 20-25, 1996.

Edmond C, "The Substitute Teacher Expert Systems in Medical Training," Medical Technology Education Conference, Orlando, FL, 7-11 July 1996.

Edmond C, "Otolaryngology Training and Surgical Simulation," AAOHNS Annual Meeting Washington DC, 1996.

Edmond C, "Expert Systems in Otolaryngology," AAOHNS Annual Meeting, Washington, DC, 1996.

Edmond C, "ENT Surgical Simulation," University of Washington, Human Interface Technology Lab, 30 January 1997.

Edmond C, "Surgical Simulation and the Use of Expert Systems in Otolaryngology Training," University of Washington, Department of Otolaryngology Grand Rounds, 23 April 1997.

Upcoming Presentations

Edmond C, Clinical Congress - Annual American College of Surgeons Meeting, Chicago, Oct 15, 1997.

Edmond C, Society of University Otolaryngologist/Association for Academic Departments of Otolaryngology, Nov 1, 1997.

Edmond C, Medicine Meets Virtual Reality, Jan 1998.

Edmond C, Computers in Otolaryngology, Baylor University, Feb 21-22, 1998.

Edmond C, Wiet G, and Bolger B, Chapter - *Virtual Environments: Surgical Simulation in Otolaryngology,* Otolaryngologic Clinics of North America, Summer of 1998.

APPENDIX B

PERSONNEL RECEIVING PAY

FROM THIS EFFORT

Lockheed Martin Tactical Defense Systems

David Heskamp, Douglas Sluis PhD, Jeffrey Miller
K. Slezak, K. Yerian, J. Prulhiere, R. Baldwin, T. Bowling, T. Thompson, H. Jordan, G. Kerr, S. Peters, J. Strott, C. Dell, K. Craddock, R. Grimaldi, K. Ohlin, J. Petrecca, R. Rex, B. Minor, R. Williams, C. Hough, T. Macklin, J. Aldstadt, C. Anderson, R. Scott, B. Robinson, V. Rosler, T. Gruzleski, C. Wasson, M. Delia, S. Owens, R. Dzurovcin, B. Schnoonover, A. Angel, V. Pearson

Ohio Super Computer Center and The Ohio State University

Don Stredney, Dennis J. Sessanna, Gregory J. Wiet, Roni Yagel PhD, Naeem Shareef

Human Interface Technology Laboratory

Suzanne Weghorst, Peter Oppenheimer, Paul Schwartz, Edward Miller, Mark Billinghurst, Sisinio Baldis

Immersion Corporation

Michael D. Levin, Ken Martin, Bruce Schena, Joe Szwaja, Sam Serna, Allison Okamura

Consultants

Robert Eisler, Robert Johnston

APPENDIX C

COMMERCIALIZATION PLAN

Commercialization Plan

In accordance with the Statement of Work, Lockheed Martin Tactical Defense Systems explored the feasibility of commercial sales of the Endoscopic Sinus Surgery Simulator. The initial plan to commercialize the device follows.

Proposed Product Goals

Lockheed Martin discussed simulator product goals with clinical consultants, medical education providers, and equipment vendors. The initial goals of this product are:

- The simulator should provide initial and continuation training for endoscopic sinus surgery (ESS) procedures.
- The simulator could support demonstrations of new equipment and techniques offered by vendors and minimally invasive surgery (MIS) equipment manufacturers. Manufacturers could also use the device to support product development.
- The simulator could support rapid and safe experimentation and provide assistance in the certification of new procedures.
- Eventually, with the addition of increased functionality, the simulator could support "mission rehearsal" of planned procedures utilizing actual patient data.

Problem Statement

Lockheed Martin investigated current otolaryngology problems suitable to the application of simulation and training technology. Analysis focused on problems encountered by practitioners, health care providers, equipment manufacturers, and certifying agencies. Our analysis yielded the following issues and problems.

Practitioners: For otolaryngology practitioners, there are two primary issues:

- Endoscopic Sinus Surgery techniques are difficult to master, involving both cognitive and psycho-motor skills.
- The field of minimally invasive surgery is growing rapidly, introducing new procedures and tools at a fast pace. Current teaching methods usually consist of a weekend seminar by the equipment manufacturer, using limited training aids to learn new procedures.

Health Care Providers: There are several areas of concern to hospitals and health care organizations:

- Currently, there is no method to verify that an otolaryngologist has mastered the psycho-motor skills necessary to perform ESS procedures. Testing methods consist of written tests, or procedures performed on an animal. These methods evaluate the cognitive aspects of the procedure, but do not evaluate important psycho-motor skills.

- There is no efficient means to quantitatively measure practitioner skills for clinical privileging. Also, the practitioner who does not perform a large number of these procedures may not keep skills current. Lack of "practice" results in the potential for serious complications to patients, additional time in the operating room, and an increase in malpractice suits.

Surgical Tool Manufacturers: Manufacturers of surgical tools and associated equipment require training and simulation technology. The Food and Drug Administration (FDA) requires manufacturers to provide practitioner training to ensure some level of competence with the equipment or procedure. Many vendors provide training with weekend seminars, often using crude training devices, or animals. Surgical equipment manufacturers have no state-of-the-art means to demonstrate product features or to aid in the marketing of the product. A high-fidelity training device would allow simulation of the new product features for sales assistance and potentially for gaining FDA approval.

Certifying Agencies: No means currently exist to quantitatively measure surgical skill in a controlled environment. Organizations such as the American College of Surgeons could possibly use a device that ascertains and registers a practitioner's skill level. A recent report by the Technology Marketing Group, Des Plaines, IL indicates that otolaryngology minimally invasive surgery procedures in the US will grow by 19% annually.

Proposed Market

The market for an ESS simulation device may be divided into the following segments:

- Medical education and teaching programs
- Health care providers and Health Maintenance Organizations
- Large otolaryngology group practices
- Equipment manufacturers and vendors
- Credentialing boards, continuing medical education providers, licensing boards, malpractice insurers

Medical Education and Teaching Programs: Current ESS training consists primarily of classroom instruction and practice with animals and cadavers. The proposed training device moves training from the laboratory into the classroom, allowing "hands on" training earlier in the curriculum. There are 126 medical schools and 270 teaching hospitals and university medical centers in the United States.

Health Care Providers and Health Maintenance Organizations: This market contains strong potential for several reasons:

- The device allows practitioners to become more adept by practicing procedures. This would result in better patient care, less time in the operating room, and higher patient case load.
- Use of the simulator would ensure that a practitioner performs a minimal number of procedures for the purpose of maintaining surgical skills.

- The combination of skills maintenance and less patient time in the operating room favorably impacts the cost of the procedure and medical malpractice costs.

Large Otolaryngology Group Practices: This market segment benefits for the same reasons as Health Care Providers and Health Maintenance Organizations. Skills maintenance is the primary selling point for large group practices.

ESS Equipment Manufacturers: The FDA is moving towards having manufacturers and vendors of medical equipment become responsible for training practitioners to use their equipment and techniques. New product and procedure training typically consists of a weekend seminar, demonstrations of the device, videos, and instruction involving simplified training devices, animals or cadavers. A comprehensive training device could allow manufacturers to become involved in credentialing.

Credentialing Boards, Continuing Medical Education Providers, Licensing Boards, and Malpractice Insurers: This market segment is potentially important as boards become more involved in ensuring that practitioners qualify to perform a growing number of MIS procedures at a base competency.

Marketing Approach

This plan builds upon the ESS device delivered to Madigan Army Hospital. Lockheed Martin will continue to refine the simulator based on comments received from simulator evaluations. Lockheed Martin has, at its own expense, procured a second device for use in further simulator development and for product demonstration. This device provides a second platform for continuous product improvement as well as the capability to demonstrate the capabilities of the product to potential customers. It is anticipated that initial sales will come from prestigious hospitals and medical schools. Medical equipment vendors have also expressed interest in the product. Lockheed Martin will continue to provide product demonstrations that incorporate the latest product improvements. Lockheed Martin is discussing long-term marketing services for this product with a firm that specializes in the marketing of medical training equipment.

APPENDIX D

Development of Trauma Models Which Describe Penetrating Battlefield Injuries to the Face and Paranasal Sinuses

8 September 1997

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Prepared for:
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1 INTRODUCTION

This report represents the deliverable for Lockheed Martin Tactical Defense Systems (formerly Loral Defense Systems-Akron), Purchase Order 6X0062 dated 15 March 1996. The effort encompassed 100 person-hours of effort and was organized into three tasks. The first task described the frequency and types of combat-related penetrating facial wounds, focusing on paranasal sinus involvement. In the second task, the range and extent of tissue response associated with these wounds is documented. In the final task, a plan leading to development of computer-based models that describe tissue disruption from combat-related penetrating facial wounds is presented.

The sources of data employed in this effort were threefold and consisted of: 1) an extensive review of data from MEDLINE, the Defense Technical Information Center, and wound ballistics literature concerning penetrating facial injuries from ballistic impact; 2) personal communication, particularly concerning the WDMET database; and 3) ongoing wound ballistics research at the Applied Mechanics and Material Sciences Group of Mission Research Corporation (Fountain Valley, CA). Major conclusions from this effort are summarized below.

Historically, the midfacial region is the most vulnerable region in the body for combat-related, penetrating wounds. Combat-related, penetrating maxillofacial wounds, particularly in the midface (upper lip to supraorbital ridge), occur far more frequently, per unit projected area, than any other region of the body. This is a trend that has been consistent through WWII, the Korean War, Vietnam and recent regional conflicts. Missile wounds of the maxillofacial region, which represent less than 2% of total projected body surface area, accounted for approximately 15% of all wounds in the Vietnam conflict. Of these combat wounds, 38% were gunshot wounds, 52% were fragment wounds, and about 10% were other types.[1] Analysis of 164 soldiers killed in the Lebanon War with Israel, representing 405 penetrating war injuries – 290 (72%) shrapnel and 115 (28%) bullet – showed that the face accounted for 22.2 percent of all penetrating injuries.[2] This is 7.3 times more than its proportion of total body area. The midface from the level of the lips to the zygomatic bones was the most vulnerable area of the body, taking 42 hits (10% of all penetrating wounds).

Combat-related penetrating facial wounds affecting the paranasal sinuses usually occur in conjunction with extensive maxillofacial or craniofacial wounds caused by high-velocity military bullets or fragments from close proximity to exploding mortar and artillery shells. These wounds typically affect large areas of the face, often involving avulsion of osseous and soft tissue. Civilian handgun and combat-related, low-velocity fragmentation wounds to the face typically involve relatively superficial soft tissue penetration, often with associated fractures of the mandible or maxillary complex. In contradistinction to high-velocity missiles, low-velocity missiles do not commonly cause significant vascular trauma. The missile will commonly push nerves out of its pathway as they are only loosely fixed in tissue and have a great deal of elasticity.[3] In these wounds, the missile often remains lodged in soft tissue and can involve the paranasal sinuses. Sinus involvement is not nearly as common in these wounds as with high-velocity wounds, however. This is probably an artifact of the large areas affected by the high-velocity military bullet or high-velocity fragmentation injury as opposed to the much more localized tissue response associated with the low-velocity handgun or low-velocity fragmentation injury.

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[1] Rich, N.M., "Evaluation of missile wounds at the 2nd Surgical hospital in Vietnam," *Plastic and Maxillofacial Trauma Symposium*, Vol. 1., St. Louis, The C.V. Mosby Co., 1969, p. 9.
[2] Gofrit, O.N., Kovalski, N., et al., "Accurate anatomical location of war injuries; analysis of the Lebanon war fatal casualties and the proposition of new principles for the designing of military personal armour system," *Injury*, 27(8): 577-81, 1996.
[3] Holt, R.G., "Wound Ballistics of Gunshot Injuries to the Head and Neck," *Arch. Otolaryngol*, 109: 313-18, 1983.

A major exception to this generalization, however, is among U.S. Army aviators, a population for which low-velocity fragmentation wounds to the face have historically been a common form of penetrating injury. Among U.S. Army aviators in Vietnam, the face accounted for over half of head and neck wounds.[4] Secondary debris from armor spall and fragmentation of transparent enclosures caused most of these wounds. The wounds (excluding the eye) tended to not be serious and involved relatively shallow soft tissue injuries. Over half the debris-related injuries to the face were caused by Plexiglas fragments.[5] This type of wound may become more prevalent as dismounted combat soldiers increasingly use transparent eye and face protection.

The range and extent of tissue response associated with penetrating facial wounds tend to be highly variable and defy segregation into neat generic categories. Often, the missile trajectory is non-linear, particularly for low-velocity events. Tissue damage that occurs in conjunction with combat-related, penetrating facial wounds tends to extend beyond the permanent wound tract, tends to promote significant bone fracture, often with ejection of secondary fragments, and in general, the resulting tissue damage may not be co-linear or even contiguous. The is due to the unique contours and complicated skeletal geometry of the face, which provides many oblique surfaces to deflect projectiles and to the tremendous variation of material properties in facial structures, which tend to promote a daunting range of tissue response during the same event. This suggests that trauma models that are sufficiently general to describe the range and extent of tissue damage associated with these wounds necessarily entails inclusion of anatomical regions outside the paranasal sinuses (independently of whether these regions are displayed or available to the end user). Presumably, some key trauma management training issues are associated with the extreme variability of these wounds and how they are affected by anthropometric differences, nuances in projectile characteristics, and variation in striking conditions.

There are several issues that significantly frustrated a general approach to the first two tasks in this effort. First, there is no national database of wound ballistics data and there is no standard format for classifying penetrating wounds. Consequently, the information that exists is often locally acquired on an informal basis and is oriented to the interests and medical specialty of the investigator. Further, the manner in which wound data is aggregated significantly biases reporting of wound statistics. Aggregation of wound data for statistical analysis depends on how the human anatomy is divided, how wounds are categorized, and precisely what population is surveyed. Wounds can be categorized in terms of entry site, anatomical structures affected, wound severity or outcome, echelon of medical care surveyed, sample size, theatre of operations, and causative agent. The resulting statistics can also be biased by the excluded categories of casualties (e.g., intracranial involvement, fatalities, "carded for record only," etc). Although this frustrates general approaches to the first two tasks, a sufficient body of anecdotal information exists from which general trends can nevertheless be discerned.

In this effort, civilian and military trauma literature was exploited to gain insight in the variations of tissue response associated with penetrating facial wounds. In general, an avulsive wound with massive tissue destruction of soft and osseous tissue characterizes a bullet from a high-velocity military rifle striking the face. The entrance wound is typically a gaping, devastated area of soft tissue, often with total avulsion of hard tissue. Low-velocity handgun wounds, however, present a totally different spectrum of injury in the facial regions. Injuries are generally non-fatal and relatively non-mutilating. The entrance and exit wounds are both small and very often the missile does not exit but is retained within the tissue. Shotgun injuries represent the entire continuum of tissue damage. At close range, severe soft and hard tissue loss, with gross mutilation of the affected structures characterize shotgun injuries. At long ranges however, shotgun injuries are relatively non-mutilating.

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[4] Malick, D., "U.S. Army Casualties Aboard Aircraft in the Republic of Vietnam (1968 through 1970)," Ballistic Research Laboratory Contract Report 257, August 1975, p. 97.
[5] Bernier, R.G., and Smith H.C., "U.S. Army Casualties Aboard Aircraft in the Republic of Vietnam (1962-1967), "Ballistic Research Laboratories Memorandum Report No. 2030, March 1970.

A helpful way to classify penetrating facial injuries is to categorize them according to whether the wound is penetrating, perforating, or avulsive. In the *penetrating wound*, the missile is retained within the injured tissue. This category can be further divided into "superficial" and "deep penetrating" injuries where the projectile penetrates deep fascia and may enter a body cavity. The *perforating wound* is where the missile passes completely through the target. By definition there is always an entrance and exit wound associated with perforating wounds. The *avulsive wound* is one in which large segments of hard and/or soft tissue are explosively ejected from the wound. Usually there is a small entrance and gaping exit wound. These wounds have the greatest amount of tissue damage. Figure 1 shows how various weapons are grossly associated with the wound categories discussed above.

PENETRATING		PERFORATING	AVULSIVE
SUPERFICIAL	DEEP FASCIA, POSSIBLY ENTERING BODY CAVITY		
Airgun			
	Civilian Handgun		
	Low-velocity fragments/spall		
			Military Rifle
			High-velocity fragment
		Shotgun	
Long Range			Close Range

Figure 1. Gross association of weapons with wound categories

Figure 2 shows an example of a penetrating wound from an airgun pellet.[6] The airgun pellet has become flattened on impact with the mandible, which is not damaged. **Figure 3** shows another example of a penetrating wound from an artillery shell fragment.[7] A Japanese 75-mm. artillery shell that exploded at a distance of 100 yards hit a soldier standing in the company area. A fragment of the shell penetrated the outer wall of the maxillary sinus and lodged in the sinus cavity. This is a good example of the relative protection afforded by bony structures to low-velocity fragments. **Figure 4** shows a schematic of an avulsive wound from a self-inflicted shotgun injury.[8] The patient required an immediate unilateral frontal lobectomy and midfacial debridement.

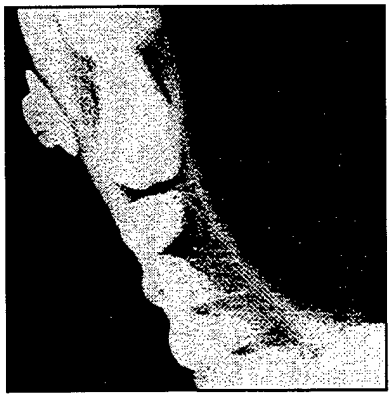

Figure 2. Airgun pellet that has become flattened on impact with the mandible

[6] Walker, R.V., and Frame, W., "Civilian maxillo-facial gunshot injuries," *Int. J. Oral Surgery,* 13: 253-277, I984, Figure 2, p. 265.
[7] Oughterson A.W., Hull, H.C., et al., "Study of Wound Ballistics – Bougainville Campaign, " Chapter V in: Coates, J.B., and Beyer, J.C., *Wound Ballistics*, Medical Department, United States Army, Government Printing Office, Washington, D.C., December 1962, Figure 179, p. 333.
[8] Vasconez, H.C., Shockley, M.E., et al., "High-energy Gunshot Wounds," *Annals of Plastic Surgery*, 36(1): 18-25, January 1996, Figure 2D and 2E, p. 22.

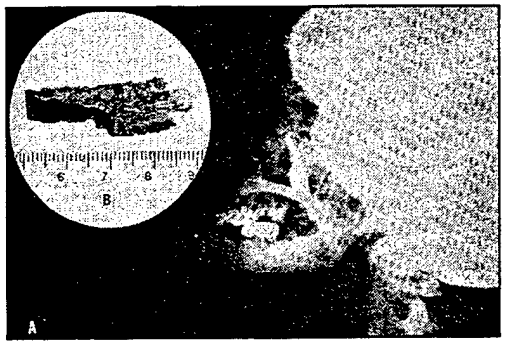

Figure 3. X-ray of skull showing artillery fragment lodged in maxillary sinus

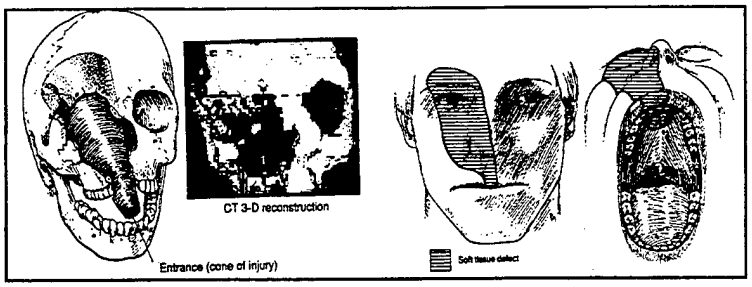

Figure 4. Schematic of an avulsive wound from a self-inflicted shotgun injury

2 TASK 1 - FREQUENCY AND TYPES OF FACIAL WOUNDS

This section is divided into three subsections. This first section reviews the various schemes of dividing the facial anatomy for the purpose of aggregating wounds for statistical reporting. The lack of commonality and lack of spatial resolution in these various schemes complicates the task of making inferences regarding the frequency of paranasal sinus wounds. The second section discusses the frequency of penetrating wounds to the face employing civilian trauma data. This data tends to be more highly refined than the corresponding military data and is therefore helpful in discussing combat-related penetrating wounds to various regions of the face in the third section.

2.1 Facial Delineation

As mentioned, there is a lack of commonality concerning the anatomical regions over which wound ballistics data is aggregated. Wound ballistics data from the military, in particular, tends to be aggregated at a fairly low level of spatial resolution. This is largely because the data is collected to design protective measures to reduce casualties, as opposed to studying remedial medical procedures. **Figure 5** shows the location of the paranasal sinuses.[9] **Figure 6** shows the most common division of the human body by the military for wound ballistic reporting.[10] Beebe accumulates some military wound ballistics data in a slightly more highly resolved format (see **Figure 7**).[11] Finally, Bernier in reporting wound data on Army aviators during the Vietnam conflict uses the facial delineation shown in **Figure 8**.[12]

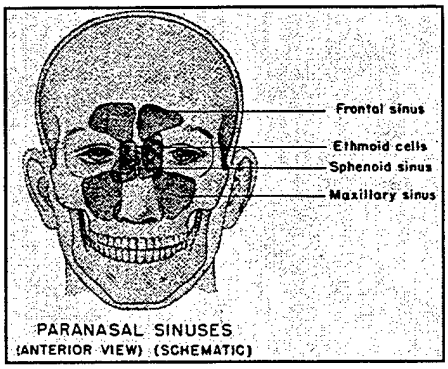

Figure 5. Anterior view of paranasal sinuses

[9] Blakiston's Illustrated Pocket Medical Dictionary, Second Edition, McGraw-Hill Book Company, Inc., New York, NY, 1960, Illustrative palte 11.
[10] Palmer, A., "Survey of Battle Casualties, Eighth Air Force, June, July, and August 1941," Chapter IX in Coates, J.B., and Beyer, J.C., *Wound Ballistics*, Medical Department, United States Army, Government Printing Office, Washington, D.C., December 1962, Figure 275, p. 560.
[11] Beebe, G.W., and De Bakey, M.E., *Battle Casualties, Incidence, Mortality, and Logistic Considerations,* Charles C. Thomas Publisher, Springfield, IL, 1952, p. 88.

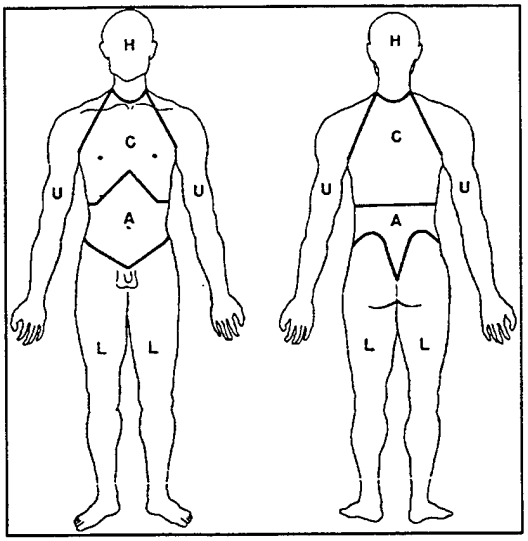

Figure 6. Delineation of human anatomy by Palmer

[12]

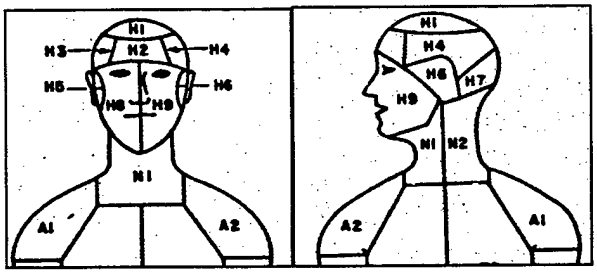

Figure 8. Bernier's division of the head and neck

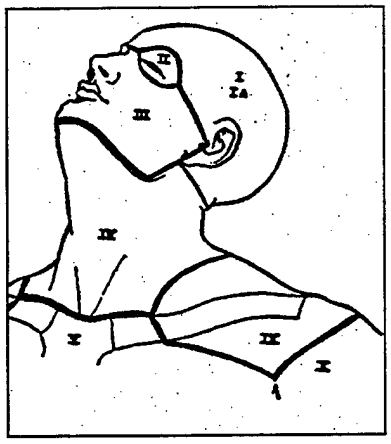

Figure 7. Beebe's topographic delineation of the head and neck

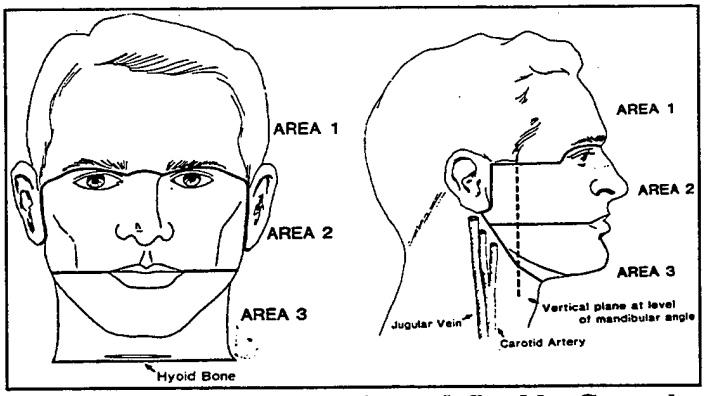

Figure 9. Anatomic boundaries as defined by Gussack

The delineation of the face for reporting civilian wound ballistics data tends to be more highly resolved since the data is often used to study treatment modalities. The most common division of the face for civilian wound ballistic studies is shown in **Figure 9.**[13] Dolin's division shown in **Figure 10** tends to emphasize the bony as structures of the maxillofacial complex,[14] whereas Kihtir's delineation (**Figure 11**) includes the orbital region well.[15]

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[12] Bernier, R.G., and Smith H.C., "U.S. Army Casualties Aboard Aircraft in the Republic of Vietnam, "Ballistic Research Laboratories Memorandum Report No. 2030, March 1970, Figure A-1, p. 99.
[13] Gussack, G.S., and Jurkovich, G.J., "Penetrating Facial Trauma: A Management Plan. *Southern Medical Journal,*" 81(3): 297-302, 1988, Figure 1, p. 298.
[14] Dolin, J., Scalea, T., et al., "The Management of Gunshot Wounds to the Face," *Journal of Trauma.* 33(4): 508-515, 1992, Figure 4, p. 513.
[15] Kihtir, R. Ivatury, R.R., et.al., "Early Management of Civilian Gunshot Wounds to the Face," *Journal of Trauma,* 35(4): 569-577, 1993, Figure 1, p. 572.

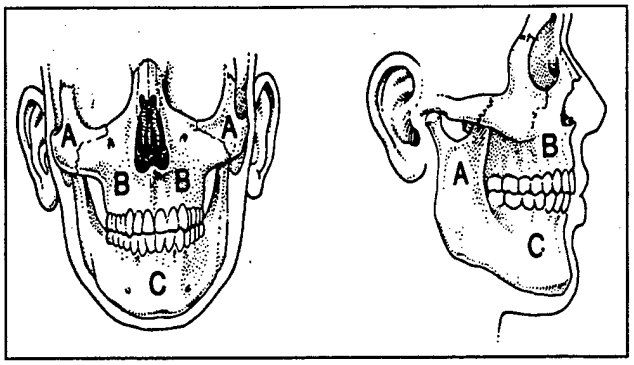

Figure 10. Dolin's Anatomical Divisions

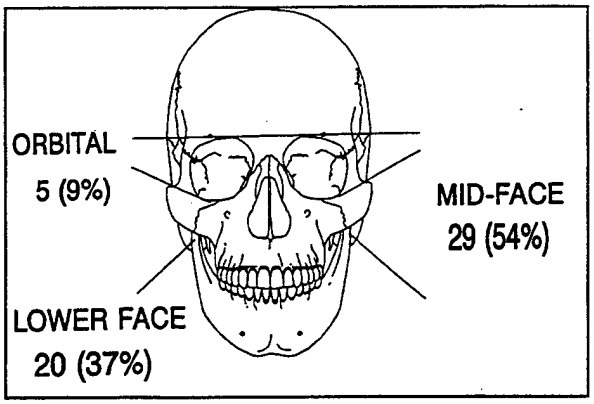

Figure 11. Kihtir's Facial Delineation

2.2 *Penetrating wounds to the face from civilian data*

Twelve retrospective studies concerning penetrating wounds to the face from civilian data are reviewed below.

2.2.1 International data[16]

Becelli, using data garnered from undocumented sources, classified maxillofacial wounds based on entrance location. He divided the face into thirds, where the upper third was above the above-roof of orbit, the middle third was between roof of orbit and upper lip, and the lower third was between lower lip and the hyoid bone. Among bony tissue fractures in the maxillofacial region:

- 42% involved the upper third
- 28% concern middle third
- 3% concern lower third
- 27% involve all three sites

2.2.2 Grady Memorial Hospital (Atlanta) from 1962-1972[17]

Bostwick retrospectively studied 547 consecutive cases of cervical and facial penetrating injuries, 277 face and 270 neck, at the Grady Memorial Hospital in Atlanta from 1962-1972. Causative agents for the wounds were 373 pistol, 111 knife and razor, 47 shotgun, and 16 from miscellaneous causes (knitting needles, biological dissection instruments). Specific injuries from Bostwick's study are shown in Table 1.

2.2.3 South Africa

Cohen and Shakenovsky retrospectively analyzed 40 cases of low-velocity handgun injuries of the face and jaw from the Johannesburg Group of teaching hospitals.[18] All cases in which the missile had penetrated the cranial cavity causing death were excluded. Other cases excluded were those in which the patient died from other or related injuries.

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[16] Becelli, R., De Ponte F.S., et al., "Firearm Injuries in Maxillofacial Region Reconstructive Surgery," *Journal of Craniofacial Surgery,* 6(6): 473-476, November 1995.
[17] Bostwick J., Schneider, W.J., et al. "Penetrating Injuries of the Face and Neck," *Southern Medical Journal,* 76(69): 550-553, May 1976.
[18] Cohen, M. A., Shakenovsky, B.N., et al., "Low Velocity Hand-Gun Injuries of the Maxillofacial Region," *Journal of Maxillofacial Surgery*, 14:26-33, 1986.

The majority of cases were due to assault (49%), followed by accidental shootings (27%) and failed suicide attempts (24%). Injuries ranged from mild to soft tissue damage without fractures to severe, comminuted fractures of the facial bones with severe soft tissue damage. Rarely were injuries life-threatening. Entrance wounds were characteristically small and well circumscribed. In 60% of the cases, the bullet did not exit and was retained within the tissues.

Table 1. Specific Injuries from Bostwick

Globe	108
Fracture of maxillary bone and sinus	64
Mandibular fractures	63
Pharynx	35
Zygoma fractures	26
Orbital fractures	26
Tongue	19
Facial nerve	11
Frontal sinus	10
Paratoid	10
Nasal fractures	10
Sphenoid sinus	7
Facial vein	5
Facial artery	4
Palate	3
Ethmoid sinus	2
Horner's syndrome	1

Injuries were divided into upper third, middle third, and lower third of the face. Upper-third injuries were above the supraorbital ridges. Middle-third injuries occurred in the area from the supraorbital ridges to the upper lip, and lower- third facial injuries involved the area between the lower lip and hyoid bone.

In 25 cases, the caliber of the bullet was known, .38 in 52% followed by .22 in 24%. The authors observed that the most severe injuries were due to the .22 caliber projectile. The .22 most likely has a lower mass and striking velocity than the .38 and therefore less kinetic energy. According to conventional wisdom (with which the author does not agree) which correlates wound severity with kinetic energy, we would expect more tissue damage to be associated with the .38. However, .22 handguns tend to use a full metal jacket (FMJ) projectile as opposed to the .38, which uses a relatively soft projectile. We may speculate that the .38 bullet probably tends to deform when it strikes bone tissue as opposed to the .22.

Most entrance wound sites were located around the mouth and chin (25%), followed by cheek (20%) and ear (15%). The cheek was the most common exit site, followed by the neck area.

Mandibular fractures varied from simple fractures to severely comminuted compound fractures with displacement of bony fragments. Of 23 mandibular fractures, 18 (78%) were comminuted fractures, while 5 were not. The maxillary complex was involved in 45% of the cases, of which 50% involved a fracture encompassing the sinuses. Ninety percent of the wounds involved single or multiple fractures of the facial skeleton. The mandible was the bone most often fractured (23 cases) followed by the maxillary complex (18 cases). Corresponding to this, fractures of the lower third of the face occurred in the majority of cases, followed by concomitant fractures of the middle and lower thirds of the facial skeleton.

Fractures of the mandible were comminuted in the majority of cases, with the extent of damage varying. In some instances, the bullet shattered the entire body or condyle of the mandible. The body of the mandible was the site most commonly affected (52%) with symphyseal, ramus, and conylar fractures the next most common sites, occurring with equal frequency (12%). Combination fractures, such as body fracture combined with dentoavelor fracture, were present in many cases. In comminuted fractures, bony fragments and pieces of tooth act as secondary missiles, causing further soft tissue damage.

Maxillary complex fractures were generally less severe than mandibular fractures. This is probably due to the relatively thin nature of the bone, which allows the bullet to pass through rather than stopping it. When the bullet passed through the mouth into the maxillary sinuses, an oroantral fistula resulted. In several cases, these

were fairly large. Similarly, several oronasal communications resulted. The tongue and roof of the mouth were the most common sites of soft tissue injury. These injuries rarely threaten the airway.

Cohen and Byes-Varley[19] reviewed 27 cases from South Africa where bullets penetrated and were retained in the maxillofacial region. Two involved the maxillary sinus.

2.2.4 Wake Forest University Medical Center, 1986-1992[20]

Forty cases of gunshot wounds to the mouth, mandible, and maxilla were treated at Wake Forest University Medical Center over 7 years, 1986-1992. The study conducted by Cole excluded patients with gunshot wounds involving only the neck or with isolated intracranial injuries. In Cole's study, 67.5% of the cases were due to assault, 17.5% accidental shooting, and 15% unsuccessful suicide. The causes of injury in 31 cases were handguns, 8 involved shotguns, and 1 involved a high-velocity rifle. Of the 40 wounds: 22 were midfacial entrance wounds, 11 involved isolated mandibular entrance wounds, and 7 were combined mandibular and midfacial entrance wounds. **Figure 12** shows the distribution of entrance wounds from Cole's study.

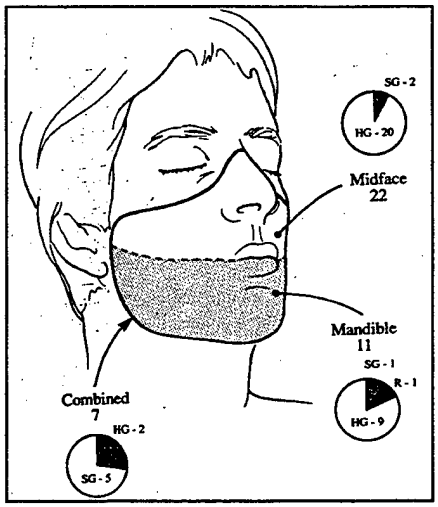

Figure 12. Distribution of entrance wounds from Cole's study

2.2.5 SUNY Health Center, Brooklyn, July 1986 to April 1991[21]

From 1 July 1986 to 1 April 1991, Dolin reviewed the cases of 100 patients with gunshot wounds to the face (98 gunshot, 2 shotgun) which were seen at the SUNY Health Center in Brooklyn. Note that gunshot wounds to the face are relatively rare, even in busy urban centers such as SUNY Brooklyn. In fact, in a discussion comment following Dr. Dolin's paper, Dr. Rao Ivatury indicated that he had seen only 39 cases of gunshot wounds to the face over four years in the Bronx.

Dolin defined a penetrating wound of the face as one where the entrance wound was located above the inferior border of the mandible and below the base of the skull. Patients whose entrance wounds were located above the superior bridge of the nose or orbital roof were considered to have transcranial wounds (**Figure 10**). Patients whose bullets entered in zones II and II of the neck were excluded. There were 10 cases of multiple gunshot wounds, four to the face. In Dolin's population:

- 35 patients needed urgent airway control in the Emergency Department
- 2 patients needed surgical airway control
- 19 sustained vascular injuries, 11 of which required therapy
- 9 suffered intracranial wounds
- 67 sustained bony injuries (110 wounds)
- 38 suffered significant neurologic injury (26 peripheral, only 10 of which were obvious at the time of initial evaluation, one spinal and 20 cerebral)
- 6 died (3 CNS, one exsanguination, and 2 sepsis)

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[19] Cohen, M.A., and Boyes-Varley, G., "Penetrating Injuries to the Maxillofacial Region," *J Oral Maxillofac Surg.* 44:197-202, 1986.
[20] Cole, R.D., Browne, J.D., et al., "Gunshot wounds to the mandible and midface: Evaluation, treatments, and avoidance of complications," *Otolaryngology – Head and Neck Surgery*, 111(6): 739-745, December 1974.
[21] Dolin, J., Scalea, T., et al., "The Management of Gunshot Wounds to the Face," *Journal of Trauma.* 33(4): 508-515, 1992.

Maxillary fractures involving the sinuses were the most common injury (33), followed by mandibular fracture (29). Closed reduction of facial fractures was the most common of the 59 procedures performed; only 3 patients underwent an open operation for facial fractures. The facial nerve was the most common peripheral nerve injured, followed by mandibular branch of the trigeminal nerve. Forty-four percent of Dolin's cases had surgical treatment, of which 25% had post-surgical complications. Results from Dolin's study for different regions of the face are shown in Table 2.

Table 2. Results from Dolin's Study

(See Figure 6 for definition of facial zones)

Facial Zone	# patients	ED Airway	CNS	Vascular	Peripheral
A	42	9 (21%)	7 (17%)	6 (14%)	12 (29%)
B	33	12 (36%)	7 (21%)	4 (12%)	6 (18%)
C	42	20 (48%)	3 (7%)	9 (21%)	11 (26%)

CNS injuries are a common complication of transfacial gunshot wounds. The most interesting aspect, however, involved the patients who had missile trajectories that traversed the base of the skull. Although initially asymptomatic, Dolin found that 9 of 15 patients (60%) had significant intracranial injuries.

2.2.6 San Francisco General Hospital, 1971 and 1978[22]

Gant and Epstein evaluated 66 cases of low-velocity gunshot wounds to the maxillofacial complex between 1971 and 1978 at San Francisco General Hospital. Patients dead on arrival (DOA) or who died within 24 hours were excluded from this study. The cases were divided into three anatomic regions, based on the wound entrance location:

- Area I: Supraorbital (36 cases)
- Area II: Midface between the level of the supraorbital ridges to upper lip (20 injuries, 12 cases of soft tissue injury only)
- Area III: Lower lip to the hyoid (10 cases)

Wounds in Gant and Epstein's population are summarized in Table 3. In their population, 59 of 66 cases were found to have an entrance wound only, with the missile expending itself in the soft or bony tissues.

Table 3. Wounds in Grant and Epstein's Population

Supraorbital, 36 cases		Mid-facial, 20 cases		Lower facial, 10 cases	
Entered cranial cavity	20	Soft tissue only	12	Facial fractures	6
CNS	13	Facial fractures	8	Soft tissue	4
Soft tissue only	4	Periorbital fractures	6	Carotid laceration	3
Ear or mastoid	3	Teeth fractures	2	Tracheostomy	2
Cranial nerves	3	Cranial nerves	2	Infection	1
Sinuses	3	Enucleation	2		
Direct ocular	3	Infections	0		
Infection	2				

[22] Gant, T.D., and Epstein, L.I., "Low-velocity Gunshot Wounds to the Maxillofacial Complex," *Journal of Trauma*. 19(9): 674-77, 1979.

2.2.7 University of South Alabama Trauma Center, June 1985 to June 1986[23]

Gussack and Jurkovich evaluated 16 cases of penetrating facial trauma treated at University of South Alabama Trauma Center from June 1985 to June 1986. The cases included 13 gunshot and 3 stab wounds. Gunshot wounds included 10 low-velocity handguns, one .357 magnum, one pellet rifle, and one 12-gauge shotgun. Injuries included 3 CNS, 4 mandibular fractures, 3 optic nerve or globe injuries, and 7 maxillary sinus fractures.

In evaluating patient wounds, Gussack and Jurkovich divided the face into three regions (see Figure 5). Area I includes the forehead and ears, and is bounded superiorly by the hairline and inferiorly by the supraorbital rims. Area II is the midportion of the face, including the area from the supraorbital ridges to the upper lip, and extending to the preauricular areas laterally. Area III extends from the lower lip to the hyoid bone. Of 16 patients reviewed, the entrance wound was isolated to Area I in three patients, to Area II in nine and to Area III in three. One patient had a gunshot to Areas I and II. The ten Area II wounds resulted in intracranial injury in one patient, optic nerve or globe injury in three, and maxillary sinus injury in seven. Three patients sustained soft tissue damage only.

2.2.8 Libya[24]

Khalil reviewed 18 patients with different types of what he classifies as "civilian" gunshot injuries to the face and jaw. The causative agents included 5 cases from rifles, 2 from handguns, 4 from shotguns, 5 from airguns, and 2 cases of shrapnel from land mines. In this population, 10 patients had soft tissue injuries and 8 had mandibular fractures with soft tissue injuries.

2.2.9 Lincoln Medical and Mental Health Center (Bronx), 1988-1992[25]

Kihtir reviewed 54 civilian patients from 1988 to 1992 with gunshot (handgun) wounds of the face treated at the Lincoln Medical and Mental Health Center in the Bronx. Suicide and shotgun injuries were excluded from this review as well as patients with entrance wounds in the frontal region. In Kihtir's population:

- 2 patients (4%) sustained multiple gunshot wounds
- 26 patients (48%) sustained single facial fractures
- 17 (31%) had multiple facial fractures
- 11 patients (20%) had soft-tissue injury without concomitant fracture
- 18 (33%) required urgent airway control and 39% non-emergency airway control
- 12 (22%) sustained CNS injuries
- 5 (9%) had vascular injuries

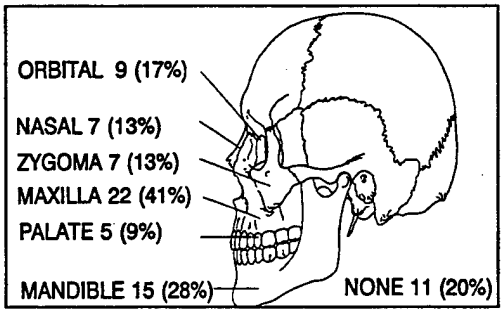

Figure 13. Proportion of bone fractures in Kihtir's population

Kihtir divided the face into the mandible and tongue (lower face); maxilla, lower portion of nose and zygoma (mid-face); and orbits and nasoethmoid complex (orbital). See **Figure 7**. The maxilla was the most commonly fractured bone (41%), followed by mandible (28%). **Figure 13** shows the proportion of bone fractures in Kihtir's population.[26]

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[23] Gussack, G.S., and Jurkovich, G.J., "Penetrating Facial Trauma: A Management Plan. *Southern Medical Journal*," 81(3): 297-302, 1988.
[24] Khalil, A.F., "Civilian Gunshot Injuries to the Face and Jaws," *British Journal of Oral Surg.* 18:205-211, 1980.
[25] Kihtir, R. Ivatury, R.R., et al., "Early Management of Civilian Gunshot Wounds to the Face," *Journal of Trauma,* 35(4): 569-577, 1993.
[26] *Ibid.,* Figure 2, p. 572.

2.2.10 King's County Hospital (Brooklyn), 1985 – 1994[27]

Lee retrospectively reviewed 35 patients treated for low-velocity gunshot wounds of the paranasal sinuses treated at King's County Hospital in Brooklyn between 1985 and 1994. All patients with isolated intracranial, neck (including zone III), orbital, or mandibular injuries were excluded from this review. The total number of sinuses was greater than 35 because many patients had more than one sinus injury. The maxillary sinus was most frequently injured, followed by ethmoid, frontal, and sphenoid. Fifteen patients had peripheral nerve injuries including the maxillary branch of trigeminal nerve (7), followed by facial nerve (6), and mandibular branch of trigeminal nerve (5). There were 3 deaths, each involved the frontal sinus associated with intracranial injury. Generally, the wounds were nonfatal and non-mutilating. Table 4 compares the location of the bullet entrance wound with the location of injury from Lee's data.

Table 4. Location of bullet entrance wound vs location of injury

Location of bullet entrance		Location of injury	
Frontal sinus	6	Ethmoid	20
Orbital	4	Maxillary	27
Maxillary	20	Frontal	6
Nasal	5	Sphenoid	5
Total	35		

2.2.11 Mount Sinai School of Medicine (Manhattan), January 1963 through December 1966[28]

Yao reviewed data from all patients (60 cases) who sustained missile wounds of the face from bullet wounds or shotgun blasts during the period from January 1963 through December 1966 who were treated at Mount Sinai School of Medicine in New York City. Wounds of the forehead and brain were excluded. Tissue injuries were classified into those that damaged bony structures and soft tissues. See Table 5. Two patients sustained facial nerve injury; one of these lesions was transient and one was permanent.

Table 5. Damage to soft tissue and bony structures in Yao's study

Bony Structures		Soft Tissues	
Mandible	25	Skin	60
Maxilla	28	Tongue	14
Zygoma	3	Pharynx	12
Cervical Spine	6	Carotid Artery	4
Palate	3	Eye	2
Nasal Bone	4	Sinus	8
Orbit	5	Salivary Gland	5
		Spinal Cord	1

2.2.12 Kentucky Chandler Medical Center between 1976 and 1993[29]

During the 18-year period from 1976 to 1993, a total of 604 gunshot wounds to the head and neck were treated at the University of Kentucky Chandler Medical Center or the Veterans Administration Medical Center. Of these, 33 patients (5.4%) were determined to have gunshot wounds to the face.

Of the total number of injuries, 73% (24 cases) were caused by shotguns. These weapons were almost entirely 12-gauge in caliber. Handguns were used in 7 cases, 5 of which were either assaults or accidental shootings. These weapons included four .38 caliber pistols, two .357 magnum handguns, and one 9-mm pistol. Only 1 patient was known to have been shot from a range of more than 10 feet. For 1 patient, the range was unknown; for the remaining 30, the range was 10 feet or less.

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[27] Lee, D., Nash, M., et al., "Low-velocity gunshot wounds to the paranasal sinuses," *Otolaryngology-Head and Neck Surgery*, 116(3): 372-78, 1997.
[28] Yao, S.T., Vanecko, R.M., et al., "Gunshot wounds of the face," *Journal of Trauma*, 12(6): 523-528, 1972.
[29] Vasconez, H.C., Shockley, M.E., et al., "High-energy Gunshot Wounds," *Annals of Plastic Surgery*, 36(1): 18-25, January 1996.

Injuries were categorized by facial region into upper (skull and intracranial), middle (maxilla and maso-ethmoid-orbital), and lower (mandible and submental). Every injury involved both bone and soft tissue, and more than half (17) involved multiple facial regions. Thirteen patients sustained permanent neurological sequelae, either sensory or motor. Table 6 shows the distribution of facial wounds according to anatomic involvement.

More than 90% of the patients in Yao's study sustained injuries to the lower face and mandible, which is a typical pattern of injury in self-inflicted wounds with long-bore firearms such as shotguns.

Table 6. Distribution of facial wounds according to anatomic involvement

Type of Injury		
Upper	8	24.2%
Midface	22	66.7
Lower	25	75.8
Upper only	1	3.0
Midface only	4	12.1
Lower only	10	30.3
Upper-midface	3	9.1
Lower- midface	11	33.3
Upper-mid-lower	4	12.1

2.3 *Combat-related, penetrating wounds to the face*

This section is divided into four subsections:

- 2.3.1 World War II and the Korean War - discusses the significance of facial wounds in WWII and the Korean War
- 2.3.2 Vietnam Conflict - discusses this issue in the context of the Vietnam conflict
- 2.3.3 Regional Conflicts - discusses this issue in the context of limited sample sizes from the Afghan and Lebanon Wars
- 2.3.4 U.S. Army Aviators - discusses the occurrence of facial wounds in WWII and Vietnam-era U.S. Army aviators.

2.3.1 World War II and the Korean War

Beebe estimates that head, neck, and facial wounds represented 21% of total casualties during WWII.[30] Of 461,258 living wounded during WWII, Beebe also estimates that 14-15% were head, neck, and facial wounds.[31] For a sample of the 7,714 wounds to head, neck, and face, the rate of facial wounds was 39.7%. (Figure 7 shows how Beebe delineated anatomical regions of the face.) From the front, the face extended from the point of the chin to the eyebrows and supra-orbital ridges. In side view, the face was demarcated from the neck by a line from external auditory meatus to the angle of the mandible and thence along the lower border of the mandible to the chin. Tables 7, 8 and 9 elaborate on the distribution of wounds for different theatres of operation by facial region and broad anatomical structure during WWII. Table 10 gives comparative information for WWII and the Korean War on the occurrence of head, neck, and facial wounds.

[30] Beebe, G.W., and De Bakey, M.E., *Battle Casualties, Incidence, Mortality, and Logistic Considerations*, Charles C. Thomas Publisher, Springfield, Illinois, 1952, Table 78.
[31] *Ibid.*, Table 81, p. 181.

Table 7. Case fatality rate of wounded (admissions to hospital and quarters) in Southwest Pacific Area, 1942-1943 by broad anatomical region and structures[34]

	# Wounded	# Deaths	% Deaths
FACE	126	7	5.6
Soft tissues only	96	0	0.0
Soft tissues and bones	30	7	23.3
TOTAL	2,602	145	5.57

Table 8. Case fatality rates for wounds (excluding living who lost no duty time) of facial region by tissues involved, all wounded in SWPA, MTO, and POA, January-June 1944[33]

Organs and Tissues	# Wounded	# Deaths	% Deaths
FACE	3,062	54	2
Eye	798	4	1
Nose	148	4	3
Mouth and other organs	158	2	1
Bones	407	19	5
Joints and muscles	7	0	0

* Of 7,714 wounds to the head, neck, and face, the face represented 39.7%.

Table 9. Distribution of 20,747 American battle casualties admitted to Fifth U.S. Army hospitals, 1 August 1944–2 May 1945, by principal wound in the head and neck[32]

	% of all Battle Casualties	% Died
Head		
Intracranial	1.95	26.00
Scalp	3.775	0
Eye and Ear	2.00	0
Neck	2.07	0.87
Maxillofacial		
Bone	1.22	1.5
Soft tissue	4.68	0.29

[32] Snyder, H.E., and Culbertson, J.W., "Study of Fifth U.S. Army Hospital Battle Casualty Death," Chapter VII in Coates, J.B., and Beyer, J.C., *Wound Ballistics*, Medical Department, United States Army, Government Printing Office, Washington, D.C., December 1962, Table 128, p. 482.
[33] *Ibid.*, Table 40, p. 112.
[34] *Ibid.*, Table 37, p. 108.

Table 10. Percent distribution for anatomical location of wound (excludes cases where specific location was not recorded) by casualty category[36]

	WWII				Korean War			
	Deaths	KIA	DOW	Nonfatal	Deaths	KIA	DOW	Nonfatal
Head	32.5	35.6	10.7	7.4	35.7	37.9	25.4	6.8
Face	3.7	3.8	3.2	7.6	5.0	4.9	5.4	9.4
Neck	4.2	4.6	2.2	1.6	4.5	5.1	1.4	2.0

Of 91 patients returned to duty from the first echelon during the Bougainville campaign during WWII, there were 293 soft-tissue wounds, 20 of which were to the face and neck. From the rear echelon, 82 patients were returned to duty with 186 soft tissue wounds, of which 17 were face and neck (excluding the eye). There were a total of 151 soft-tissue wounds and fractures in 58 patients evacuated to the U.S., of which the face and neck accounted for 12 wounds.[35]

Of 1,105 consecutive casualties with penetrating craniocerebral trauma suffered in the Korean War during the period 1 September 1950 to 31 August 1952, 43 (3.9%) were found to have facio-orbito-cranial wounds (4). Seventeen of these cases (40%) had involvement of the paranasal sinuses.[37]

2.3.2 Vietnam Conflict

Hardaway estimates that approximately 24% of those wounded in Vietnam had head and neck wounds.[38] Kovaric, reviewing 3,954 Vietnam-era patient records encompassing 5,577 wounds occurring between February-November 1967, estimated that 15.7% were head and neck wounds.[39] Based on 750 patients treated at the 2nd Surgical Hospital located in the central highlands of the Republic of Vietnam, over the nine-month period from January to October 1966, Rich estimated that of 1,178 wounds, 123 (10%) occurred in the head and neck regions.[40] In comparison to Rich's analysis of casualties, which were mostly survivors, Jones[41] and Felitis[42] in studying casualties admitted to hospitals, indicated lower percentages of head and neck wounds, 8.2% and 11.3%, respectively. According to a WDMET[43] study encompassing 925 wounds, the body region most frequently sustaining penetrating wounds was the head and neck with 260 wounds (28.10%). These discrepancies in the rates of head, neck, facial wounds probably reflect biases in the casualty population surveyed (echelon of medical care, wound severity, and predominate small-arm threats in the locality) as opposed to real trends. Table 11 compares the percent of fatal and non-fatal wounds for the head, neck and face during WWII, the Korean War, and the Vietnam conflict using large sample sizes over long time intervals.

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[35] Oughterson A.W., Hull, H.C., et al., "Study of Wound Ballisitcs – Bougainville Campaign," Chapter V in Coates, J.B., and Beyer, J.C., *Wound Ballistics*, Medical Department, United States Army, Government Printing Office, Washington, D.C., December 1962, Figure 179, p. 331.

[36] Reister, F.A., "Battle Casualties and Medical Statistics – U.S. Army Experience in the Korean War," Surgeon General, Department of the Army, Government Printing Office, 1973, Table 45.

[37] Dillon, J.D., and Meirowsky, A.M., "Facio-Orbito-Cranial Missile Wounds," *Surg. Neurol.*,4: 515-518, 1975.

[38] Hardaway, R.M., "Vietnam Wound Analysis," *Journal of Trauma,* 18(9): 635-642, 1978.

[39] Kovaric, J.J., Aaby, G., et al., "Vietnam Casualty Statistics," Arch Surg. 98: 150-52, 1967.

[40] Rich, N.M., "Vietnam Missile Wounds Evaluated in 750 Patients," *Military Medicine*, 9-22, 1968.

[41] Jones, E.L., Peters, A.F. and Gasior, R.M., "Early Management of Battle Casualties in Vietnam," Arch Surg, 97, 1-15.

[42] Felitis, J.M., Jr., "Surgical Experiences in Combat Zone," Amer J Surg., 119, 275-278, 1970.

[43] "Evaluation of Wound Data and Munitions Effectiveness in Vietnam, Volume I" Final Report for the Joint Technical Coordinating Group for Munitions Effectiveness, December 1970, Table III.

Table 11. Percent fatal and non-fatal wounds to the head, neck, and face[44]

War	Sample Size	Head, Face, and Neck
WWII	116,649	25%
Korea	90,841	19
Vietnam	23,396	15

The head and neck comprise between 9 and 12% of total body projected surface area. Assuming non-aimed fire and random hits, one would predict that those areas should receive 9 to 12% of all hits. However, Table 11 shows that the head and neck have generally received a disproportionately high number of hits. This is undoubtedly because the head is preferentially exposed in combat as the soldier constantly monitors his environment by means of his eyes, ears, and nose to enhance his chances of survival.

Table 12 seems to indicate that the incidence and severity of neck and facial wounds is increasing. Rich estimates that missile wounds of the maxillofacial region accounted for approximately 15% of all wounds in the Vietnam conflict. Of these combat wounds, 38% were gunshot wounds, 52% were fragment wounds, and about 10% were other types.[45] This overall rate of maxillofacial wounds estimated by Rich is greater than wounds to the thorax and abdomen combined. This however is probably an artifact of the fact that body armor worn during Vietnam which would reduce the occurrence and severity of thoracic and abdominal wounds from fragments.

Table 12. Percent distribution for head versus face and neck wounds (KIA, DOW, and living wounded) for U.S. Army in WWII, Korea, and Vietnam[46]

War	Head	Face & Neck
WWII		
Killed	40	9
DOW	20	6
Living Wounded	8	8
Korea		
Killed	38	10
DOW	25	7
Living Wounded	7	11
Vietnam		
Killed	34-46	8
DOW	46	46
Wounded	17	17

In a WDMET[46] analysis of the regional distribution of fatalities from 500 consecutive autopsies (July 1967 - November 1968), it was estimated that 12 wounds (2.4%) were facial. Bellamy estimates of all facial injuries in the WDMET database, 30% involved the eye (one-half resulted in loss of the eye), 30% were injuries involving the jaw, with mandibular fractures being most common; and 20% involved the maxilla or zygoma (i.e., sinuses). The remainder involved the external ear or tympanic membranes.[47]

Matthews,[48] during a 12-month tour of duty in a field hospital in Vietnam analyzing 92 patients with penetrating wounds to the brain discovered that these wounds not infrequently involve the paranasal sinuses and orbit. There were 16 paranasal sinus injuries among Matthews's 92 cases of cranio-cerebral trauma.

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[44] Carey, M.E., "An Analysis of U.S. Army Combat Mortality and Morbidity Data," *Journal of Trauma.* 28 (1, Suppl.), S183-189, 1988, Table III.

[45] Rich, N.M., Evaluation of missile wounds at the 2nd surgival hospital in Vietnam, Plastic and Maxillofacial Truama Sympositum, Vol. 1., St Louis, The C.V. Mosby Co., 1969, p. 9.

[46] Evaluation of Wound Data and Munitions Effectiveness in Vietnam, Volume I" Final Report for the Joint Technical Coordinating Group for Munitions Effectiveness, December 1970, Table I.

[47] Bellamy, R., Personal Communication, 16 June 1997.

[48] Matthews, W.E., "The Early Treatment of Craniocerebral Missile Injuries: Experience with 92 Cases," *Journal of Trauma,* 12(11): 939-954, 1972.

2.3.3 Regional Conflicts

Gofrit[49] analyzes 405 penetrating war injuries (290 shrapnel and 115 bullet) in 164 soldiers killed in the Lebanon-Israeli War. The body part with the greatest density of penetrating injuries was the face, with 22.2 percent of all penetrating wounds. In particular, the mid-face, from the level of the lips to the level of the zygomatic bones, was especially vulnerable, sustaining 42 wounds, which was 10% of all penetrating wounds. Thirty-two penetrating wounds were found in the upper face, above the zygomatic bones, and 19 in the lower face below the level of the mouth. Table 13 shows the distribution of head and neck wounds from Gofrit's study as a function of causative agent.

Table 13. Distribution of head and neck wounds among 164 fatalities in Lebanon-Israeli war

Region	Shrapnel	Bullet	Total Hits	Presented Area
Face	57 (19.6%)	33 (28.7%)	90 (22.2)	3%
Head	19 (6.6%)	17 (14.8%)	36 (8.9%)	3%
Neck	10 (3.4)	1 (0.9)	11 (2.7%)	3%
Total	290	115	405	3%

Rautio reported on 200 Afghan war wounded in International Red Cross Hospital in Quetta. He found 25 (12%) head injuries, of which 14 had penetrating brain trauma. Of nine facial injuries, eight were relatively insignificant and one suffered a gunshot wound, destroying the nose and upper lip and fracturing the mandible and hard palate.[50]

2.3.4 U.S. Army Aviators

Three studies, two from the Vietnam era and one from WWII, are reviewed in this section. The first Vietnam-era study encompasses 2,946 wounds occurring between 1962 through 1967.[51] The face represented 208 (7%) wounds, and with the exception of "unspecified leg wounds" was the most frequently wounded region of the body during this interval. Among these 208 facial wounds were 30 eye wounds.[52] Tables 14 and 15 summarize these results. As is evident from these tables, debris caused most of the wounds but was a negligible cause of fatal and serious wounds. Half of debris resulted from Plexiglas fragmentation. Of 2,946 total wounds

Table 14. 1962-1967 – Percentage distribution of head and neck wounds by cause versus location, fatal and serious wounds[53]

Anatomical Region	Bullet	Other Projectile	Aircraft Debris	Other Causes
Helmet area	34.0	2.1	0.0	36.1
Head (unspecified)	22.7	3.1	0.0	25.8
Face (including eye)	15.5	7.2	2.1	24.8
Neck	11.3	1.0	1.0	13 3
Total Head and Neck	83.5	13.4	3.1	100.0

[49] Gofrit, O.N., Kovalski, N., et al., "Accurate anatomical location of war injuries; analysis of the Lebanon war fatal casualties and the proposition of new principles for the desing of military personal armour system," *Injury.* 27(8): 577-81, 1996.

[50] Rautio, J. and Paavolainen, P., "Afghan War Wounded: Experience with 200 Cases," *Journal of Trauma.* 28(4): 523-25, 1988.

[51] Bernier, R.G., and Smith H.C., "U.S. Army Casualties Aboard Aircraft in the Republic of Vietnam (1967-1967), "Ballistic Research Laboratories Memorandum Report No. 2030, March 1970.

[52] *Ibid.*, Table D-22.

[53] Bernier, *Op Cit.*, Table 4.29, p. 68.

Table 15. 1962-1967 – Percentage distribution of head and neck wounds by cause versus location, fatal and serious wounds[55]

Anatomical Region	Bullet	Other Projectile	Aircraft Debris	Other Causes
Helmet area	10.0	2.2	3.1	15.3
Head (unspecified)	6.4	2.2	1.4	10.0
Face (including eye)	6.0	16.7	**34.1**	56.8
Neck	4.7	3.3	9.9	17.9
Total Head and Neck	27.1	24.4	48.5	100.0

between 1962 and 1967, 253 (8.58%) were due to Plexiglas fragments. Forty-six of these wounds (1.5%) affected the face only.[54]

The second Vietnam-era study encompasses 5,186 wounds occurring between 1968 through 1972.[56] Of these wounds, 446 (8.6%) affected the face, not including the eyes, and 399 (90%) were not serious.

In this study, the head and neck was initially divided into forehead, face, skull, ear (mastoid), neck, and "unspecified." However, the forehead, skull, and ear were subsequently grouped into the "helmet area" for reporting purposes. In this casualty population, the face accounted for over half of the head and neck wounds, but only 25% of the fatal wounds and 15% of the serious wounds.[57] As in the previous study, facial wounds, not including eye injuries, and with the exception of "unspecified leg wounds," were the most frequently sustained wound of the body during this interval.

Finally, Palmer, in a study of U.S. aviators during WWII, documented the striking locations of 85 penetrating facial wounds from Plexiglas fragments occurring in 75 WIA casualties.[58] See **Figure 14.**[59]

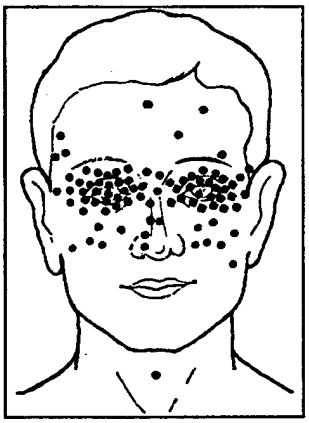

Figure 14. Location of 85 wounds due to Plexiglas fragments in 75 WIA casualties

[54] *Ibid.*, Table 4.20, p. 61.
[55] Bernier, *Op Cit.*, Table 4.29, p. 68.
[56] Malick, D., "U.S. Army Casualties Aboard Aircraft in the Republic of Vietnam (1968 through 1970)," Ballistic Research Laboratory Contract Report 257, August 1975.
[57] *Ibid.*, p. 97.
[58] Palmer, A., "Survey of Battle Casualties, Eighth Air Force, June, July, and August 1941," Chapter IX in: Coates, J.B., and Beyer, J.C., *Wound Ballistics*, Medical Department, United States Army, Government Printing Office, Washington, D.C., December 1962.
[59] *Ibid.*

3 TASK 2 - TISSUE RESPONSE AND DAMAGE

This section is divided into two subsections. The first discusses gross characteristics of tissue damage associated with various categories of small arms and the second provides several supporting case histories.

3.1 Gross Characteristics of Tissue Damage Associated with Various Categories of Small Arms

As previously mentioned, there are some gross characteristics of penetrating wounds that can be associated with various classes of weapons. At the less severe end of the spectrum are low-velocity missile threats that include handguns, airguns, and low-velocity fragments from spall and strikes by shrapnel or fragments from a long distance following detonation of a high-energy munition. At the severe end of the spectrum are high-velocity missile threats that include military rifles and strikes by shrapnel or fragments in close proximity to an exploding mortar or artillery shell. Shotguns, which will be discussed separately, encompass the entire spectrum of injury, depending on distance, choke, and projectiles fired.

3.1.1 Low-velocity projectiles

Low-velocity projectiles cause laceration and crushing of tissues. The surrounding structures are not usually affected and injuries are generally not serious unless a vital organ or vessel is directly struck. Both the entrance hole and residual channel are smaller than the diameter of the missile because of elastic recoil of the soft tissues. An exit wound, if present, is often ragged and slit-shaped due to yaw of the projectile in the tissues, or fragmentation if bone or teeth have been encountered. Low-velocity bullets are usually made of lead alloy and deform and partially disintegrate in tissue. Sometimes these bullets are surrounded by a copper or cupronickel jacket which may become dislodged or break up in the body.

In a retrospective analysis by Cohen and Shakenovsky of 40 cases of low-velocity handgun injuries of the maxillofacial region, due to assault followed by accidental shootings and failed suicide attempts; injuries ranged from mild to soft tissue damage without fractures to severe, comminuted fractures of the facial bones. In some cases soft tissue damage was severe. Rarely were injuries life threatening or even mutilating and entrance wounds were characteristically small and well circumscribed. In 60% of the cases the bullet did not exit and was retained within the tissues. [60]

The characteristic feature of low-velocity wounds is that the injury is confined to the permanent wound tract and to tissues and organs directly penetrated by the missile. Airguns, for example usually result in little morbidity unless a delicate structure such as the eye is perforated. Due to the elasticity of the soft tissues, the narrow wound channel closes spontaneously with little damage to adjacent structures. When the dense bone of the mandible is encountered, the pellet is flattened but does not usually have sufficient energy to fracture the bone (see Figure 2). However, an airgun pellet may penetrate the thin bone of the maxilla and enter the maxillary antrum or nasal cavity.

On impact with the mandible by a low-velocity projectile, the bone is often comminuted, but the projectile usually has insufficient energy to expel the fragments which are held in place by the periosteum and soft tissues. The thin bones of the maxilla are more susceptible to injury and may be severely comminuted and displaced around the missile track. Gunshot wounds of the maxilla produce fractures that rarely follow the classic Le Fort pattern, but alveolar fracturing is common with associated oroantral and oronasal communication. Low-velocity gunshot wounds, however, tend to penetrate and divide maxillary bone tissue and

[60] Cohen, M.A., Shakenovsky, B.N., et al., "Low Velocity Hand-Gun Injuries of the Maxillofacial Region," *Journal of Maxillofacial Surgery*, 14:26-33, 1986.

fracture the cortical surface of the mandible. Teeth, dentures and the projectile itself may also fragment and be widely displaced in surrounding tissue.

In many cases, the bullet is deflected off bony structures at a tangent and follows an irregular pathway. Frequently, low-velocity missiles from handguns break up and leave small metal particles in the projectile's path. The pathway may often be seen radiologically by the presence of lead fragments along the bullet track. Low-velocity missiles may also tend to be deflected by such structures as vessels, nerves, and facial planes. The path of these slowly moving projectiles will therefore be much more erratic, sometimes having no relation to entrance and exit wounds. Dr. Robert McCormack (Rochester, NY) in the *Comments on Discussion* section of Gant's study on low-velocity gunshot wounds to the maxillofacial complex[61] makes the following clinical observation: "We had very many instances of extremely bizarre pathways." Entrance and exit wounds do not necessarily go in a straight line for these wounds since the bony structures of the maxillofacial complex cause ricocheting effects. In contrast, high-velocity missiles cut straight through soft tissues and fracture bones with relative ease.

The amount of tissue injury produced by these low-velocity missiles is considerably less than that from high-velocity weapons, which is an important consideration in the management of these injuries. The entrance wound usually is smaller than the diameter of the bullet and expected to heal without discernible scarring. The rich blood supply of the face allows conservative debridement of the soft tissue injury. The infection rate is low with civilian gunshot wounds in contrast to high-velocity bullet injuries, which require aggressive debridement of devitalized tissue and delayed wound repair.

In contradistinction to high-velocity missiles, low-velocity missiles also do not commonly cause significant vascular trauma. The missile will commonly push nerves out of its pathway as they are only loosely fixed in tissue and have a great deal of elasticity.

Unique contours and variation in properties of the bony tissues govern the interaction of penetrating projectiles with midfacial structures. Nahum derived tolerance levels of the facial bones from a series of impact experiments on cadavers. Selected facial bones were impacted with varying forces. A total of 116 impact experiments were performed with the following ranges of tolerance levels for facial bones: nasal bones – 20 to 75 lb, maxilla – 150 to 300 lb, zygoma - 200 to 650 lb, and the mandible – 550 to 900 lb. These results are represented in **Figure 15**.[62] Similar results are shown in gravity units (G's) in **Figure 16** from Swearington.[63]

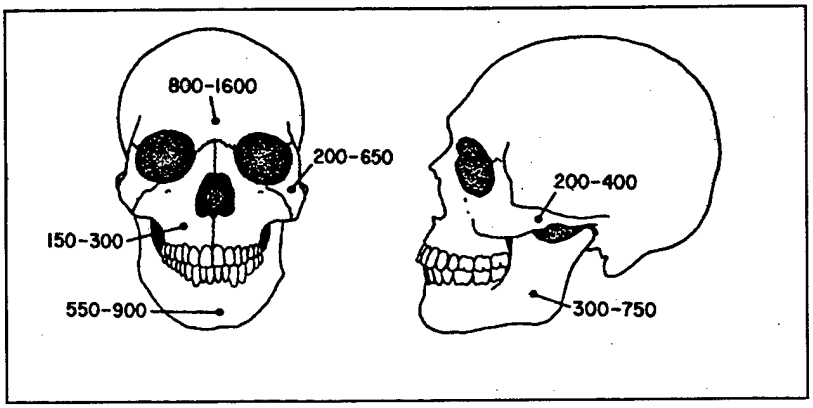

Figure 15. Ranges of tolerance levels for facial fractures (lb)

[61] Gant, T.D., and Epstein, L.I., "Low-velocity Gunshot Wounds to the Maxillofacial Complex," *Journal of Trauma*. 19(9): 674-77, 1979.
[62] Nahum, A.M., "The Biomechanics of Maxillofacial Trauma," *Clinics in Plastic Surgery*, (2)1: 59-64, January 1975, Figure 7, p. 63.
[63] Swerington, J.J., "Tolerance of the Human Face to Crash Impact," Reprint #65-20, Federal Aviation Agency, Oklahoma City, OK, 1964.

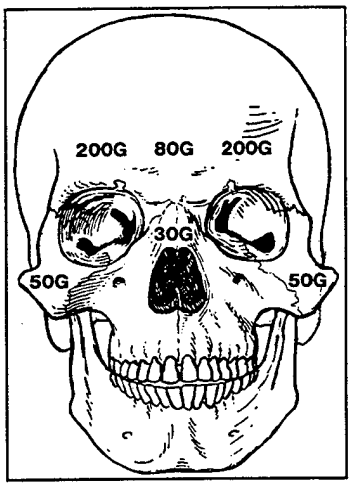

Figure 16. Threshold accelerations required to fracture selected facial bones, in gravity units (G's)

3.1.2 High-velocity projectiles

High-velocity projectiles cause much more disruption of the tissue than low-velocity projectiles. A wound from a high-powered military rifle, for example, is characterized by an avulsive wound with massive tissue destruction of soft and osseous tissue. The entrance wound is a gaping, devastated area of soft tissue, often with total avulsion of hard tissue. Impact of a high-velocity missile on bone and teeth will produce numerous secondary missiles, all of which have the potential for high-velocity movement within tissues.

The effect of cavitation on the living body is to pulp the soft tissues, disrupt small blood vessels, and produce extensive areas of necrosis. Larger blood vessels and nerves are elastic and may be pushed aside, but the intima may be damaged even though there is no external sign of injury, and nerve axis cylinders may disintegrate. Thrombosis and stasis in vessels further increase the extent of the necrosis and leakage of plasma causes tense edema. However, the soft tissue bulk of the face is smaller and has a better blood supply than other parts of the body and is less sensitive to those destructive effects.

The underlying intricate bony architecture of the maxillofacial region is very susceptible to damage by high-velocity missiles, whether by direct contact or by the outward expansion of the temporary cavity. Fragments of calcified structures may be scattered widely within the tissues, or be expelled from the body, leaving a large ragged exit wound. High-velocity projectiles are rarely retained intact in the facial region unless they have been impeded by previous contact with other structures or by ricochet. Jacketed bullets usually pass through the body without changing shape, but the jacket, if thin, occasionally fragments into small pieces even on impact with soft tissues and may be widely scattered to the full extent of the temporary cavity.

3.1.3 Shotgun

Civilian shotgun injuries are also characterized by severe soft and hard tissue loss, with gross mutilation of the affected structures. In a retrospective review by Sherman and Parrish[64] of 534 patients with gunshot wounds admitted to John Gaston Hospital (Memphis) from 1948 through 1959 (patients who died shortly after admission were excluded), 152 patients had shotgun wounds and 382 patients had wounds produced by a variety of other firearms. Sherman and Parrish found that the mortality from shotgun wounds was more than twice that of other gunshot wounds. In this study, 89 of 152 shotgun injuries were to the head, neck, and extremities, compared to 163 of the 382 gunshot wounds.

In general, Sherman and Parrish found that at ranges exceeding 7 yards, wounds were *penetrating* with projectile penetration of subcutaneous tissue or deep fascia. At 3-7 yards, wounds were *perforating* with projectiles perforating deep fascia into body cavities. At ranges under 3 yards, the wounds manifested extensive mutilating tissue destruction.

Wounds from a shotgun fired from over 20 feet are similar to those of multiple slow-velocity weapons. On the other hand, shotgun blasts at close range are more like high-velocity weapons. As the range decreases, the pattern of pellets striking the target will have a smaller diameter. At very close range, the size of the pellets makes little difference, since they act as one large mass traveling at a high velocity. It is also important to realize that a shotgun's wadding acts as a separate missile at close range and may escape detection since it is radiotranslucent.

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[64] Sherman, R.T., and Parrish, R.A., "Management of Shotgun Injuries: A Review of 152 Cases," *Journal of Trauma*," 3: 76-86, 1963.

In self-inflicted wounds from shotguns and rifles that are long barreled, the gun is often placed under the chin. This requires the head to be tilted backwards a fair distance for the patient to be able to reach the firing mechanism and discharge the gun. This commonly results in massive loss of the mandible, lower lip, floor of the mouth, and tongue, and may result in massive loss of the palate, maxilla, nose, nasal passages, and one or both eyes. Unless placed in the mouth, however, intracranial involvement is uncommon.

3.2 *Selected Case Histories*

The following case history is reproduced from Mektubjian[65] concerning a wound from a low-velocity handgun. A 26-year-old female patient was struck in the face by a bullet from a small-bore pistol at a distance of one meter. The entrance wound was situated behind the right nasolabial sulcus, with the exit wound in the vestibulum oris in the area of upper first molar tooth. The crowns of the upper and lower right molars were fractured off, comminuted and embedded through multiple puncture wounds in the root of the tongue and the floor of the oral cavity. Tissue lacerations were present along the right mandibulo-lingual sulcus and pterygomandibular fold. The continuity of the mandible was not interrupted. Two large fragments from the inner lingual cortex of the angle area of the mandible, and portions of the alveolar process were embedded in the neighboring soft tissues.

The lateral and P-A X-rays of the facial skeleton revealed numerous metallic foreign bodies varying in shape and size, grouped in the right half of the mandible, and one – the largest – projected along the left lower mandibular border. The fractured crowns of the right upper molars and the scattered shadows of fragments of teeth and displaced roots were visible.

In the course of a further X-ray study, a defect in the body of the third cervical vertebra was discovered. The projectile had deflected twice, once on touching the mandibular bone, and a second time, by the supero-anterior edge of the third cervical vertebra.

On the tenth day, a greatly deformed lead bullet was removed. It was lodged beneath the sternocleidomastoid muscle, laterally and in close proximity to the neurovascular bundle of the neck, which showed no evidence of traumatic change.

Facial wounds are fatal when hemorrhage causes aspiration, or displacement of the severed structures causes airway obstruction. A representative case is that of a man wounded by a bullet that entered the left jaw, transected the tongue, and fractured the maxilla and mandible. The exit wound was on the right side of the face. The wound tract measured 285 mm. Aspiration of blood caused death.[66]

Bostwick[67] in his retrospective study of 547 patients treated at Grady Hospital for penetrating wounds to the face and neck (refer to Section 2.2.2), discovered only one death from facial injury due to upper airway obstruction from rapidly expanding retro pharyngeal hematoma not managed by tracheostomy or exploration. Active bleeding from a vascular injury to the face can be significant because of the diffusely vascular nature of the facial structures and the presence of major blood vessels within the upper neck. Avulsed or fragmented teeth and/or dentures can also result in aspiration of teeth with subsequent laryngospasm or bronchial obstruction.

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[65] Mektubjian, S.R., "Low Velocity Gunshot Maxillofacial Injury Combined with a 'Blind' Wound of the Neck," *Journal of Maxilliofacial Surgery*, 9: 85-55, 1981.
[66] "Evaluation of Wound Data and Munitions Effectiveness in Vietnam, Volume I" Final Report for the Joint Technical Coordinating Group for Munitions Effectiveness, December 1970, p. 2-14.
[67] Bostwick J., Schneider, W.J., et al., "Penetrating Injuries of the Face and Neck," *Southern Medical Journal,* 76(69): 550-553, May 1976.

Upper facial bony structures may afford considerable protection from intracranial involvement and low-velocity projectiles. Gussack reports of a 12-year boy who was shot in the mid-forehead with a pellet rifle; however, there was no intracranial penetration and the pellet was lodged in frontal sinus.[68] The WDMET[69] reports of a casualty walking on a sweep maneuver through the jungle when a fragment struck him from a Claymore mine. His helmet was not hit. He sustained a comminuted fracture of the frontal sinus, but there was no dural penetration.

Dillon[70] also reports of a case involving a fragmentation wound to the facio-orbito-frontal region. The projectile entered the inner canthus of the right eye. The missile passed through the right orbit and frontal sinus. It then penetrated the floor of the right anterior fossa, lodging in the right frontal lobe. There was rhinorrhea as well as cerebrospinal fluid leakage from the entry site. Loss of cerebrospinal fluid from the nose indicates that there is an open road for bacteria or air to the meninges and brain. Cerebrospinal rhinorrhea is seen most often in wounds about the frontal sinuses; however, its immediate recognition is often obscured by the profuse bleeding accompanying these wounds. In this case, a metallic fragment was removed from the frontal sinus.

4 TASK 4 - TRAUMA MODEL DEVELOPMENT

Given the extreme variability of facial wounds and the associated projectile interactions, an important feature of a surgical training simulator for these wounds would be to recreate some of this variability as well as the non-visible mechanical damage that occurs. Unfortunately, this requires either a database of wounds that have been cross-sectioned and digitized, (which does not exist) or a set of models that describes or infers the relevant phenomenology at an acceptable level of detail and fidelity.

Development of maxillofacial penetrating wound models affecting the paranasal sinuses should proceed in three stages. The first stage would address low-velocity projectiles with striking locations in the maxillofacial region in close proximity to the paranasal sinuses where the projectile is retained in soft tissue. During this initial stage, bony structures would be modeled as rigid and the projectile would be non-deforming. The focus on this initial phase would be to model the projectile trajectory in soft facial tissue, bleeding and swelling, and create an interface with the anatomical model used by the simulator. This interface would map a database of relevant material properties and provide a Boolean algebra to remove and/or modify regions of polygons in the simulator. One idea would be to create regions of polygons that overlay the initial anatomy of the simulator but are not displayed until a flag is registered.

During the second phase, bone interaction would be introduced. Initially, dynamic fracture thresholds of relevant bony features would be approximated in terms of energy density per unit time thresholds. This would necessarily be determined experimentally and would require embalmed human facial bones (or skulls) to be supplied as GFE. Existing data on dynamic bone fracture of facial structures has been developed almost exclusively to support analysis of automobile crashes. In general this data is not useful for ballistic impact since the pulse width of the forcing function in both cases differs by at least two orders of magnitude. In fact, the governing parameters for these two scenarios are probably entirely different in that the ballistic damage is impulse driven, whereas the crash scenario is driven by stress/strain excursions in the bony structures.

Ballistic experiments would have to be implemented where energy density would be measured and related to fracture mode. The scale, distribution, and ejection velocity of bone fragments would be measured in a skeletal

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[68] Gussack, G.S., and Jurkovich, G.J., "Penetrating Facial Trauma: A Management Plan. *Southern Medical Journal*," 81(3): 297-302, 1988, Case 3.
[69] "Evaluation of Wound Data and Munitions Effectiveness in Vietnam, Volume I" Final Report for the Joint Technical Coordinating Group for Munitions Effectiveness, December 1970, p. 2-31.
[70] Dillon, J.D., and Meirowsky, A.M., "Facio-Orbito-Cranial Missile Wounds," *Surg. Neurol.*,4: 515-518, 1975.

muscle tissue simulant as well as projectile penetration thresholds and residual exit velocities. Fragment geometry, distribution, and initial velocities would then be modeled stochastically based on experimental results. This will result in relevant features of the wound presentation being continually different to the end user. Ideally, the skulls would be from soldier-aged populations, x-rayed to determine thickness of cortical layers. A separate series of ballistic experiments would be implemented to refine and verify existing bone deflection models developed at Mission Research Corporation (MRC). At this stage of the modeling, the striking location of the projectile would still be in the vicinity of the maxillary complex. The emphasis of the modeling effort at this stage would be to model the three-dimensional non-rigid bone interaction and rigid body kinematics of the projectile that is still modeled as non-deforming.

The third stage of the modeling effort would relax the assumption of a non-deforming projectile and permit projectile striking locations anywhere on the face that could affect the paranasal sinuses. Equations of state (EOSs) would be developed for relevant bony structures on the face. The EOSs would be used in a hydrocode to determine relevant wound features and parametric sensitivities. Results form these hydrocode models would be formatted as a library of base models with associated "look up" tables to perturb the base models. Since the overall thrust of this effort is to interface with an endoscopic simulator, it is probably not relevant to model avulsion of tissue or interaction of high-velocity fragments or military rifle bullets (particularly when it is considered that overwhelmingly, penetrating wounds from military rifles occur at close range, under 20 yards).

The first phase of the proposed effort is approximately 5 man-years over 18 months. The second phase is on the order of 9 man-years over 30 months, and the final phase is approximately 5 man-years over 18 months. Many aspects of the proposed effort necessarily advance the state of the art relative to the biomechanics of bone fracture. A literature review for another project revealed that there are only 12 articles published in the word literature relative to ballistic trauma to bones. The most recent article was published in the mid-1980's in the People's Republic of China. In all cases, the reviewed articles dealt with fracture of long bones by ballistic events. Therefore, in many respects the proposed work will be unique.

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APPENDIX E
Formal Evaluation of the Madigan Endoscopic Sinus Surgery Simulator

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ABSTRACT

The Madigan Endoscopic Sinus Surgery (ESS) Simulator is a state-of-the-art procedural simulator developed by a multi-institution team led by researchers at Lockheed Martin. It includes force-feedback instrument and virtual endoscope interfaces developed by Immersion Corporation, and 3-D models of the paranasal sinus anatomy derived from the Visible Human dataset by researchers at the Ohio Supercomputer Center, supplemented by a variety of instructional aids, such as hoops for navigation paths and targets for injection sites. We describe here the results of our formal evaluation of the simulator, led by researchers at the Human Interface Technology (HIT) Laboratory at The University of Washington. Formative evaluation efforts throughout the development phase of the project informed the system design and user interface requirements for the simulator. Summative evaluation of Version 1.2 of the system was conducted during the second phase of the project, with an emphasis on its validity as an ESS simulator. Run-time and survey data were collected on three groups of subjects who ran through a common protocol which progressed through three basic surgical tasks: navigation, injection, and dissection. A group of non-physician subjects performed the tasks on an abstract virtual model with the instructional aids. A group of non-otolaryngologist MD subjects progressed through this abstract model to an intermediate model with the instructional aids embedded in the paranasal anatomy. A group of otolaryngologists ranging from second-year residents to experienced senior staff ran through the abstract and intermediate models, followed by an advanced model of the anatomy with no instructional aids. The procedural validity of the simulator is supported by the strong correlation between performance on the ESS simulator and degree of prior ESS experience, and by the subjective evaluations by the experienced ESS surgeons. A novel path visualization technique is also introduced, with a set of quantitative measures of endoscope and instrument path performance. These measures provide initial evidence for the validity of the system-generated scoring algorithms based on time, completeness, and accuracy.

1 INTRODUCTION

The use of computer simulation as a training tool for surgical procedures has been motivated by the success of computer simulation flight training as well as the high cost of medical education. In recent years, advances in interactive graphics and virtual reality technology have greatly enhanced our arsenal of instructional tools (Caird, 1996), moving these systems toward more general commercial graphics platforms.

A recent survey of prior research in surgical simulation suggests that each surgical procedure has a unique set of simulation requirements (Edmonds et al., 1997). Research thus far includes abdominal laparoscopy (Cover et al., 1993; Hon, 1994; Merril, 1994; McGovern et al., 1994); limb surgery (Chen et al., 1992; Pieper et al., 1991); eye surgery (Peifer et al., 1994; Sagar et al., 1994); plastic surgery (Pieper, 1989); gastrointestinal endoscopy (Baillie et al., 1992; Bard, 1990; Gillies et al., 1992; Poon et al., 1988); anesthesiology (Good et al., 1993); epidural anesthesiology (Bostrom et al., 1993; Stredney et al., 1996); and interventional radiology procedures (Dawson et al., 1996). Much of this recent work in medical simulation has received impetus from the leadership of both DARPA (Satava, 1996) and the Army Medical Command.

Wickham (1994) summarizes the need for these novel and extensive training techniques for endoscopic surgery skills:

> Evaluation of new operative competence is urgently needed because of the rapidity of changes in interventional treatment. Training programmes must be established so that interventionists' training is similar to that of airline pilots. A surgeon or radiologist should not be allowed to treat patients with sophisticated and potentially dangerous instruments without the experience of simulated operations and closely supervised procedural training. Fully equipped training centers should be established with simulator laboratories where interventionists can develop the different hand-eye coordination required for the transition from open to endoscopic techniques . . . The need is urgent: the traditional methods of "see one, watch a video, do one" are completely inadequate preparation for minimally invasive techniques . . . A theoretical evaluation of competence by written or oral examination is totally insufficient to determine whether a clinician has gained the manual ability to carry out complex open or endoscopic surgery.

The motivation for medical training simulators is clear. It is important, however, to ask: Do they work? Is the simulator effective as a training device? What skills do students learn most effectively? Do the skills learned in the simulated training transfer to the operating room? How fast do students learn? How does an hour of simulator time compare to an hour of traditional training methods? Are these simulators currently cost effective? If not, when will they be cost effective for use in medical schools? And how can simulators best be integrated with medical school curriculum?

To answer these questions, formal evaluation of surgical simulation systems is essential. Without answers, one remains uncertain as to whether students are receiving surgical training or merely learning to be good simulator users.

The evaluation study described here has been guided by the work of many others in the field. As Hoffman et al. (1996) suggest, we have included the end users during the formative stages of the simulator design, a vital step in establishing educational goals and curriculum design. In developing

our evaluation criteria we have taken into account both objective and subjective considerations (Robb, 1997), relied heavily on the basic surgical proficiency measures of time and accuracy (Johnson et al., 1996), and incorporated much of our evaluation protocol into the simulator itself (Hon, 1996; Kaufmann, 1997).

1.1 Simulator Overview

The Madigan Endoscopic Sinus Surgery (ESS) Simulator uses virtual reality technology, a force feedback (haptic) display, and 3D computer-based anatomy models as a tool to teach a variety of skills needed to perform such surgery.

The heart of the system is a 3D model of the human nasal sinus anatomy derived from the National Library of Medicine's Visible Human Database. Researchers at the Ohio Supercomputer Center (OSC) created segmented surface models of the sinus anatomy from photographic cryosections of the male dataset. The Lockheed Martin team then added stochastically generated surface textures to complete the anatomical model.

This model can be rendered in real time (15-30 frames per second, depending primarily on anatomical position) on a Silicon Graphics (SGI) Onyx System and viewed at NTSC resolution on a standard video monitor, thus simulating the view that a surgeon would see of a video endoscopic display.

To interact with the model and perform the simulated surgery, students in training use a pair of 6-degree-of-freedom input devices developed by Immersion Corporation. One such device represents the video endoscope and the other represents the surgical instrument, such as an injection needle or a forceps (Rosenberg and Stredney, 1996). An external view of an experienced ENT surgeon operating the system can be seen in Figure 1. Note that the position of the surgeon relative to the endoscopic monitor and simulated patient emulates a typical clinical configuration.

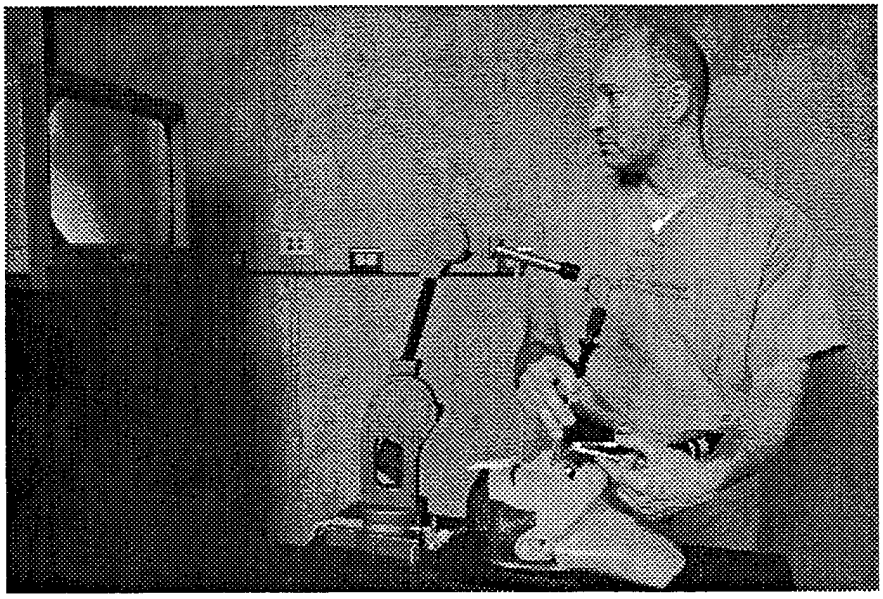


Figure 1. Operative Configuration of the Madigan Endoscopic Sinus Surgery Simulator

As the student manipulates the input devices, the simulator tracks the position and orientation of the devices, updates the positions and orientations of the virtual endoscope and virtual instrument, manipulates the virtual anatomical model accordingly, and displays the resulting virtual endoscopic view on the monitor. In addition, the system tracks the opening of the forceps handle of the instrument input device. All together, the system measures 13 degrees of freedom of the student's input.

The physical input devices are designed to resemble the feel of an endoscope and forceps and are assembled with a latex replica of a human head. The endoscope input device resides outside the head, while the instrument input device is inserted into the nostril of the latex head and attached to the position tracker inside the head. In addition to displaying the simulated endoscopic view, the system computes the forces that the sinus tissue would apply to the tip of the instrument during surgery and applies the computed force to the instrument input device, via mechanical coupling within the mannequin's head.

The proctor's console provides an interface to the run-time system parameters, along with optional radiographic views of the current anatomy and optional performance feedback summaries for the trainees.

Training Aids

Optional 3D graphical overlays are superimposed on the endoscopic view to provide performance aids for the student. These overlays include a path of circular hoops representing the desired endoscope trajectory, bullseye targets representing the desired injection sites, and text labels identifying anatomical feature landmarks.

The system provides voice audio feedback representing the current status of the surgical procedure, as well as a simulated heartbeat which responds to certain user actions.

Training Tasks

Students using the system are instructed to perform a simulated surgical procedure consisting of three subtasks: navigation, injection and dissection. In addition to archiving the frame-by-frame position of the devices, the system measures the time required to perform these tasks, as well as the accuracy with which they are performed, to generate an evaluation of the student's overall performance.

Three versions of the procedure were developed corresponding to three skill levels: novice, intermediate, and advanced. The primary differences among these procedures are the type of geometric model used and the presence of training aids.

The novice procedure uses a simplified abstract model of the anatomy consisting of several spheres inside an open box. Intermediate and advanced procedures use the more complex surface sinus model generated by OSC. Novice and intermediate procedures use the training aids described above, whereas the advanced procedure is performed without benefit of these aids (to more accurately simulate the target procedure).

1.2 Evaluation Overview

Evaluation efforts for this project fall into two general categories:

- "Formative" evaluation, which attempts to provide design specification input to the development team during the development process
- "Summative" evaluation, which assesses the success of that effort by formally analyzing the effectiveness of the system

Each of these activities is discussed in detail in the following pages.

2 FORMATIVE EVALUATION

Throughout the development of the ESS simulator, the Human Interface Technology Laboratory (HITL) team worked in close collaboration with Dr. Charles Edmond, staff otolaryngologist at Madigan Army Medical Center (MAMC) to perform ongoing formative evaluation and make design recommendations to the development teams at Lockheed Martin, OSC, and Immersion Corporation.

The methods of approach for the formative evaluation phase included the following:

1) Endoscopic video analysis to determine simulator performance requirements

2) Geometric complexity requirements analysis

3) Prototype anatomical modeling

4) Development of spatial awareness aids, interface features and rendering approaches

5) Development of a prototype simulator with an integrated expert system assistant

6) Development of a surgical training curriculum to be embedded in the simulator

7) Survey of medical experts to determine feature and curriculum priorities

Dr. Edmond provided the core of domain expertise in sinus surgery. After a few weeks of study, the rest of the HITL team had gained a basic familiarity with sinus anatomy and surgical issues. During this time Dr. Edmond gained familiarity with the computer graphics tools available at HITL for use in prototyping simulator design and computer-assisted surgery applications.

2.1 Design Requirements Analysis

2.1.1 Frame Rate Requirements

Method: Representative sequences of live video endoscopic sinus surgery were digitized and manipulated. These sequences were selected to include surgical interaction with tissue as well as to highlight early and late operative anatomy. Image degradation due to the scanning process itself was minimal.

We then re-recorded the scanned video at the following frame rates: 30 frames per second (fps), 15 fps, 10 fps, 5 fps, 2 fps, and 1 fps. These recordings were reviewed by expert surgeons to assess the minimum frame rates required for the ESS simulator.

Results: To the extent possible, 30 fps should be maintained. For surgical dissection, a minimum of 15 fps (preferably 30 fps) should be maintained; temporary slowdowns to 10 fps during deformation and dissection may be tolerable for certain instruments and maneuvers (e.g., side-biter, but not sickle knife). Frame rates lower than the 10 fps minimum may cause disorientation in navigation.

2.1.2 Geometric Complexity Requirements

We applied the following guiding principles in assessing the geometric complexity requirements:

- Visual fidelity requirements are task driven.
- The task and subtask relevant to each individual varies based on level of training and experience.
- Three categories of expertise were defined: novice, intermediate and expert. Tasks and subtasks were delineated for each category, and fidelity requirements proposed.
- Accurate anatomic representation (visual realism) and 3D spatial awareness are two of the most critical aspects for effective cognitive development. This was felt to be important across all levels of training and experience for endoscopic sinus surgery.
- The development of psycho-motor skills necessary for successful endoscopic sinus surgery may require less visual realism and more 3D spatial awareness.
- Low-level visual realism might be less distracting to the novice, and therefore advantageous for both developing and assessing a user's psycho-motor skills.
- Varying degrees of visual fidelity are not only helpful, but necessary to develop the cognitive and psycho-motor skills for sinus surgery.

Methods: To help assess the geometric complexity requirements for the anatomical models, we generated a prototype anatomical model using the following technique:

A 3D triangular mesh was generated by texture mapping an actual video endoscopic image onto a flat mesh surface and vertically displacing each vertex of the mesh in proportion to the brightness of texture at that vertex. We then varied the resolution of the mesh and evaluated the quality of the resulting images. This model is a fairly rough approximation, since video brightness does not precisely correspond to geometric distance from the endoscope. Specular highlights in the texture create spike artifacts in the model. These were eliminated by painting over the highlights in the texture.

Geometric complexity requirements were determined by visual inspection of the resulting simulation mock-ups by the project domain experts. Evaluation criteria included:

- Ability to identify features
- Subjective evaluation of photo-realism
- Potential for simulator miscues

Results: We concluded that given the performance of the rendering system, frame rate was a critical performance requirement. When the initial versions of the anatomy model were delivered from OSC, the frame rate did not meet our specification. The geometric complexity of the model was reduced until the specified frame rate was achieved. The geometric complexity requirement was essentially a function of the frame rate requirement and the rendering performance of the hardware and software engines.

The anatomical model developed for the ESS simulator adequately served its function. We noted considerable improvements in quality and efficiency of the model over the duration of our

evaluation. Upon each release of a new model, our team would evaluate the model for rendering efficiency and fidelity. Dr. Edmond would suggest modifications to the model, and these would be executed in subsequent releases. The addition of textural cues greatly enhanced the apparent geometric detail without sacrificing rendering speed.

2.1.3 Prototype Anatomical Modeling

Prototype anatomical virtual models were developed by Edmond and Oppenheimer using the Alias modeling package. The purpose of these models was to provide guidelines in the design of the patient-specific data-driven models produced by OSC, as well as to determine the necessary rendering and interface features for use in the simulator.

Methods: The geometry of these prototypes was based on cadaveral section photographs taken primarily from sinus anatomy atlases and surgery textbooks (Rohen and Yokochi, 1983; Rice and Schaefer, 1988). In one case, sections were scanned into the computer, and mapped onto parallel image planes. These image planes were then used as templates for drawing surface contours on the planes. These contours were then lofted into surfaces. Additional contour curves were added and edited as needed, based on Dr. Edmonds's observations.

In other cases, freeform surface contours were drawn orthogonal to the scanned image plane. The scanned image was then projection texture mapped onto the resulting lofted surface. Although less geometrically accurate, this technique enabled photographic texture maps to be used in the final evaluation model.

Results: These prototype models provided the basis for experimenting with navigation aids, interface features and rendering approaches as described in the next section.

2.1.4 Interface Features and Rendering Approaches

The following design experiments using the prototype anatomical models resulted in recommendations and demonstrations of candidate features to be included in the development of the ESS simulator:

- Use of texture
- Use of transparent or wireframe surfaces to reveal obscured anatomy
- Use of orientation cues to assist in navigation
- Use of tubular paths of hoops as a navigation aid
- Use of targets as an injection aid
- Use of crosshairs overlaid on instruments to represent orientation, and to assess distance from anatomy
- Use of patient face model
- Anatomical segmentation and interactive selective segment display
- Displaying endoscope position on CT scans as a navigation aid
- Integration of expert system training aids

Texture Mapping

The use of texture mapping offers several benefits. Texture maps can represent detail that would be too expensive to model as polygonal geometry. Photographic texture maps add to the realism of the model.

Texture also provides additional depth cues. If two parallel surfaces overlap from a given perspective view, then they may have the same shading coefficients in the lighting calculation. Without texture maps, the two surfaces would be rendered with the same pixel values; therefore the boundary between them would be indistinguishable. By placing texture maps on the surfaces, the discontinuity between the surfaces can be detected more easily, as a consequence of texture discontinuity.

In conditions of extreme ambient lighting, even non-parallel surfaces may have similar shading. Texture mapping can reveal subtle differences in orientation and distance from observer. In "real life" these shading ambiguities are also noticeable if the surfaces are of uniform texture. Real-life objects with even subtle surface textural features are more readily discerned than smooth, textureless objects.

Methods: Several texture mapping methods were applied to the models. In some cases an attempt was made to align the texture with the underlying model geometry; such textures included anatomical features. In other cases, the textures were closeup details of tissue type, such as mucosa, and did not include anatomical structures.

Results: On the basis of our experiments, we recommended the use of texture mapping in the target simulator. Since the polygonal resolution of the final models generated from the Visible Human database is as fine as the possible textures derived from the same data, detail texture had to be added algorithmically. Such texture, although not photo-realistic, does add to the realism of the simulation as well as improve the surface boundary visibility as described above.

Transparent and Wireframe Surfaces

By rendering outer surfaces transparently or in wireframe, the system can display otherwise obscured portions of the anatomy. This allows students to view anatomical landmarks prior to revealing them through dissection. These landmarks may include anatomy that should not be dissected (such as the lamina, optic nerve, or skullbase). Revealing them may enhance spatial awareness training, thereby preventing a severe surgical error. This feature is not currently implemented in the target simulator.

Orientation Cues

By displaying a world-stabilized orthogonal grid or crosshairs, the user can determine the orientation of the endoscope with respect to the patient. This feature is not currently implemented in the target simulator.

Tubular Path of Hoops

By displaying a tubular surface whose axis is the desired trajectory of the endoscope, the system can provide a navigation tool to the user during surgical simulation. We experimented with two different rendering modes for the tube: a partially transparent surface with alpha-mapped

latitudinal rings, and wireframe latitudinal hoops oriented orthogonal to the axial path. The target simulator uses the latter rendering mode (hoops).

Injection Targets

Bullseye targets of concentric rings, rendered as flat shaded polygons, can be placed on the anatomy at points of injection. These targets provide cues in the novice and intermediate modes of the simulator.

Crosshairs Attached to the Instrument

By attaching polygonal crosshairs to the tip of the virtual instruments, the system visually represents the relative orientation of the instrument with respect to the endoscope. If a grid texture is mapped onto the crosshairs, the user can assess the distance between the instrument and the anatomy by counting the grid lines between the instrument tip and the intersection between the crosshair and the tissue surface. Grid marks deeper than the tissue surface are obscured and will not be visible. This feature was not incorporated into the current implementation of the simulator.

Patient Face Model

A polygonal surface representation of the patient face was added to the virtual model. This face model provides the student with a position and orientation cue, as well as providing additional realism.

Anatomical Segmentation, and Interactive Selective Segment Display

The prototype anatomical model built in Alias was constructed in segmented pieces, corresponding to recognizable anatomical features. This pre-segmentation allows one to selectively display certain parts of the anatomy as well as to highlight selected anatomical features at run time. In addition, virtual tissue segmentation permits collision detection with procedurally meaningful objects. The model based on the Visible Human dataset required an editing process to segment the surface anatomy.

Displaying Endoscope Position on CT Scans as a Navigation Aid

As originally conceived, the user interface to the system made use of an auxiliary CT view, in addition to the virtual endoscopic view of the anatomy. The system has the optional capability of updating the auxiliary CT image view with a crosshairs indicator of the current endoscope position. Although not used by the subjects in the current evaluation study, this feature is available and may be useful for future training protocols.

Prototype Simulator with Expert System Assistant

In parallel with this development project, HIT Lab researcher Mark Billinghurst extended his work with Jesus Savage-Carmona on intelligent multi-modal environments to create a prototype sinus surgery simulator with an integrated expert system assistant (Billinghurst et al., 1996). Working with Oppenheimer and Dr. Edmond, Billinghurst developed a system which incorporates knowledge of the endoscopic procedure into a structured rule base, interprets the user's multi-modal inputs (currently voice and virtual endoscope position) and interacts with the user dyadically. While performing the simulated procedure, the user can query the system about anatomy and the specifics of the procedure, asking the system to identify features or demonstrate maneuvers. In turn, the

system recognizes the user's actions, and can provide vocal and visual feedback, as well as warnings when the user is about to execute a dangerous maneuver.

Although the system architecture is somewhat different, this prototype simulator provided ground work demonstration for certain features of the target surgical simulator, including navigation through the sinus cavity from an endoscopic viewpoint, use of abstract graphical overlays as a navigation aid, and embedding of surgical task sequences into simulator.

2.1.5 Iterative Testing

In addition to these design experiments based on prototype modeling, the HIT Lab served as a test site for successive versions of the anatomical model and the simulation system. Having the target hardware platform (SGI onyx) in-house made iterative evaluation a viable and useful approach. In particular, the proximity of the lab to MAMC made it relatively easy for the evaluation team to consult with Dr. Edmond regularly on simulator features and system performance.

Upon receiving each release of the ESS simulator, the HITL team would compile a list of feature enhancements, known bugs and other observations. This list would be prioritized by Dr. Edmond and returned to Lockheed Martin for inclusion in the subsequent release.

Haptic System Emulator. Instrument tracking and force feedback displays were not integrated into the earliest test releases of the simulator. A menu-driven "haptic system emulator" (HSE) provided a graphical user interface to navigate the position and orientation of the endoscope and instrument, as well as to select the instrument type and control the open/close parameter. The HSE consisted of up, down, left, and right buttons, sliders and radio buttons. Although not driven by a spatial input device, the HSE did allow for precisely controlled navigation, and also proved useful in positioning navigation aids within the model.

Although initially developed as a prototype testing tool , the HSE may have some commercial potential as well. Customers desiring a lower-cost system that does not require a complete 6-degree - of-freedom interface device could use a HSE to perform the surgical tasks (albeit in a way that does not capture many of the targeted clinical skills of the Madigan system). In this case the up, down, left, and right buttons could be replaced with a mouse-based interface or other commercial graphical input device.

2.2 Evolution of the Training Framework

During the early phases of the project we examined several other surgical simulator systems to look for places to improve the state of the art. What we noticed was that although these systems were making advances in anatomical modeling and user interaction, they were missing a structured educational component. In general these systems simulated a specific surgical domain or task only and were therefore "orphaned" experiences in the educational process.

We concluded that in order to be of significant educational value, one had to not only embed the simulator in the existing academic curriculum, but also develop curriculum within the simulation itself. This would not only serve the educational process but would also facilitate our evaluation of the educational effectiveness of the simulator.

The prevailing paradigm in surgical education is usually summarized as: "See One, Do One, Teach One." Our goal was to improve on this paradigm by taking the "See One, Simulate Many, Do One"

approach that had proved effective in the domain of flight training. To achieve this, we needed to develop a curriculum structure.

2.2.1 Task Analysis

Working with Dr. Edmond, we developed a taxonomy of ESS simulation objectives and simulator performance and interface features. Our objective, which proved far too demanding, was to elicit estimates from experienced ESS surgeons of the desirable system performance requirements for each training task. This approach did, however, provide us with a framework for approaching the issues of curriculum design in this domain.

2.2.2 ESS Domain Expert Survey

Twelve experienced ESS staff surgeons from several leading otolaryngology training programs were surveyed by Dr. Edmond to assess their judgments of the primary simulation requirements for physicians performing ESS procedures. The primary objective of this survey was to determine the curriculum needs and perceived importance of several of the candidate features of the system early in its development.

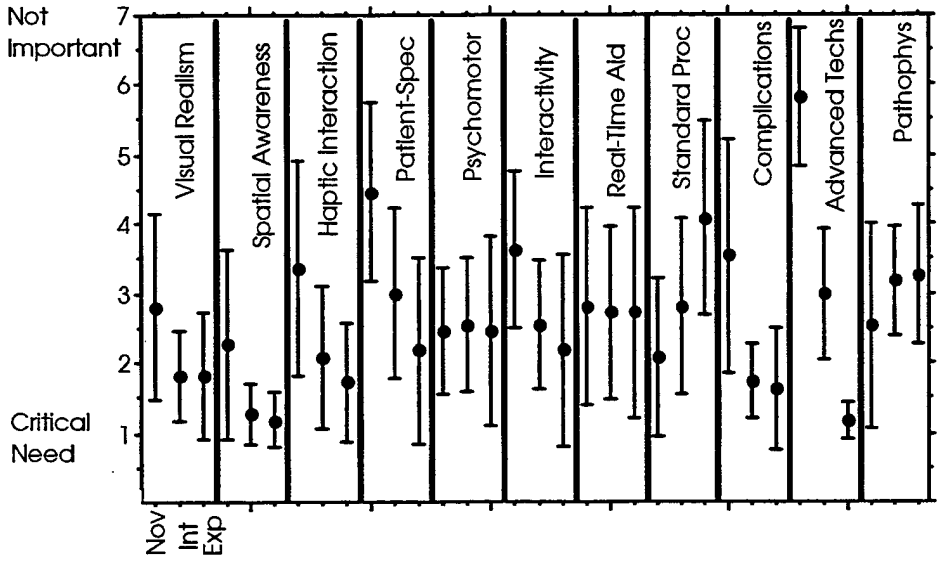


Figure 2. Mean survey response ratings (with 95% error bars) of 11 training and operational needs, for three hypothetical target groups (novice, intermediate, and experienced ENT physicians).

These domain experts were asked to rate the relative importance (from "critical need" to "not important") for 11 simulator characteristics: visual realism, spatial awareness training, haptic interaction, patient-specific modeling, psychomotor training, real-time interactivity, real-time (intra-operational) performance aids, standard surgical procedures, complications, advanced techniques, and pathophysiology.

They were also asked to assess the value of these characteristics for target subjects at three levels of ENT experience: novice (i.e., junior residents), intermediate (senior residents), and expert

(experienced ENT surgeons). Results of this survey are summarized in Figure 2, which indicates the mean rating for each characteristic for the three target groups, on a 1-7 scale.

As can be seen from this graph, these experts deemed "spatial awareness" the most crucial training need (of those presented in the survey) for all levels of subject experience, although "advanced techniques" were seen as equally critical for the experienced ESS target group. With the exception of "standard procedures" and perhaps "pathophysiology," all requirements were seen as equally important for all target levels or more important with increasing ESS experience.

It is interesting to note that almost all of these characteristics were rated on the "important" end of the scale. The characteristics deemed least important for simulation were "advanced techniques" and "patient-specific modeling" for the novice group, and "standard procedures" for the advanced group. In addition, "real-time interactivity", "haptic interaction" and training in "complications" were seen as of only moderate importance for ESS novices.

Finally, it should be noted that these survey respondents were overwhelmingly favorable toward the development of an ESS training simulator. While one or two expressed skepticism about any technological solutions, most respondents noted in their open-ended comments that this was an interesting and useful endeavor, and that the field had a need for such a system.

2.2.3 Simulator Integration

A considerable amount of effort was spent during the development phase on establishing a "curriculum wrapper" for the simulator. We initially envisioned the simulator as embedded within a multimedia training system which would provide a meaningful context and set the protocol for the trainee.

The development team elected instead to integrate relevant aspects of the emerging ENT curriculum into the simulator itself and to postpone further efforts to develop a total curriculum "package." The reasons for this included:

- Development of a full-blown ESS curriculum was beyond the scope of this phase of the project.
- It became apparent that a staged protocol approach was necessary to make the simulator effective as a training context.
- Useful techniques emerged (such as the use of navigation hoops and injection targets) which could be integrated relatively easily.

The final product of the formative stage of the project was, in fact, more thoughtful with respect to an integrated ENT curriculum than had originally been anticipated and appears to be more useful as a training tool than other virtual reality medical simulators which have emerged in recent years. Its validity as a procedural simulator and its utility for training are evaluated in the following sections.

3 SUMMATIVE EVALUATION

After delivery and installation at the HIT Lab of Version 1.2 of the system by the Lockheed Martin development team, the evaluation team began a "shakedown" of the system and testing protocols with the three targeted subject groups (described below). Midway through this phase the system was relocated to MAMC for further analysis by staff and resident ENTs.

The primary goals of this phase of the evaluation effort were to:

- Validate its utility as an ESS training environment
- Assess the usability of the system
- Provide additional iterative feedback to the development team

The methods of investigation and results of this phase are described below, followed by a set of recommendations for further system development and evaluation derived from these findings. In a planned follow-on phase, the primary focus of the evaluation effort will be on assessing the degree and nature of any transfer of this training to the real ESS operating environment (the ultimate objective of the simulator).

3.1 Methods

3.1.1 Subjects

Subjects were solicited from three distinct groups: (1) non-physicians with general intelligence and psychomotor abilities roughly comparable to the average otolaryngologist; (2) non-ENT physicians from a variety of specialties; and (3) ENTs with a wide range of ESS experience. We focused on these three groups in order to establish a baseline and asymptote for the evaluation of the efficacy of the simulator in training otolaryngology residents.

The first two groups also allowed us to "shake down" the system and research protocols without sacrificing valuable ENT resident subjects, and provided baseline scores for untrained/unfamiliar subjects. Finally, the non-ENT physician group could provide us with some valuable input about the extensibility of the simulator to non-ENT applications.

Non-Physician Group: Twelve volunteers from the University of Washington College of Engineering comprised the non-physician group. These subjects ranged in age from 23 to 54, and included graduate students, professional staff and faculty. All had had some experience with simulation and virtual reality. None had previously used an endoscope or attended medical school.

Non-ENT Physician Group: Eight University of Washington MDs from specialties other than otolaryngology provided extensive feedback on the simulator design and utility for other medical and surgical tasks: 3 video endoscopic surgeons, 2 radiologists, 1 neurosurgeon, 1 cardiologist, and 1 anesthesiologist. Four of them also provided us with complete trial performance data.

ENT Staff and Residents: Twelve staff and resident ENTs (1 female, 11 males) from MAMC served as subjects. The subjects in this group ranged in age from 28 to 46, with a mean age of 35.2 years, and a standard deviation of 6.15 years. One was left-handed, 10 right-handed, and the handedness of one was unknown.

ENT experience for this group broke down as follows:

- 4 staff (with an average of five years of training, six years of practice and more than 100 ESS procedures performed)
- 3 R2s (with an average of 1-5 ESS procedures performed or observed)
- 1 R3 (with 6-20 ESS procedures performed or observed)
- 2 R4s (with an average of 21-100 ESS procedures performed or observed)
- 2 R5s (with an average of 21-100 ESS procedures performed or observed)

Eight subjects had had occasional videogame experience, two reported playing videogames once, and two reported never playing videogames. Eleven subjects had had no virtual reality experience, while one reported occasional VR experience. Ten reported having no other simulator experience, while one reported one simulation experience and another reported "occasional" simulation experience. Because of the low incidence of prior experience with these systems, these factors were not evaluated further for this group.

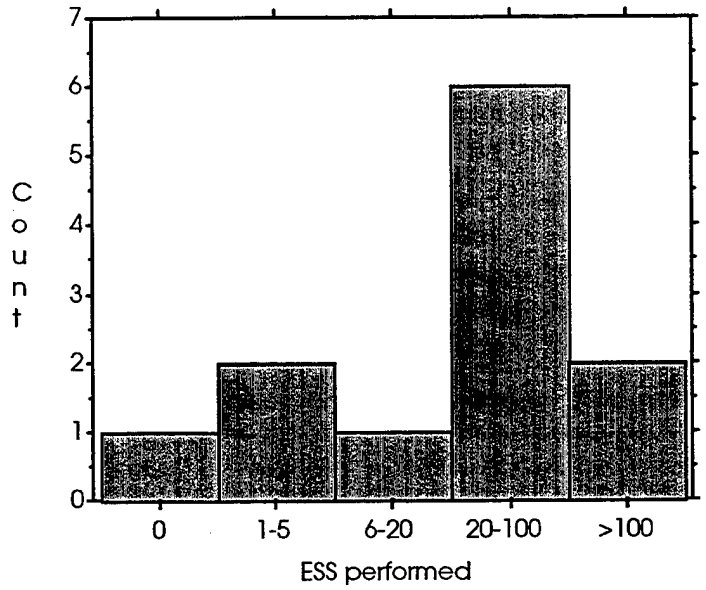


Figure 3. Frequency distribution of the reported number of prior ESS procedures performed by subjects in the ENT group.

Figure 3 shows the distribution of the number of prior ESS procedures performed by the subjects in this group. The two reporting "1-5" procedures were observational only.

3.1.2 Procedures

All subjects proceeded through a common protocol for one or more sessions, involving:

- General orientation and consent form
- Pre-session background questionnaire (Appendix H)

- Instructions and orientation to the simulator and tasks
- One or more proctored simulation trials using one of the three training models
- Post-session debriefing and questionnaire (Appendix I)

All trials were videotaped for later analysis and "think-aloud" comments. Subjects were free to terminate the session at any time.

Models

Three models were constructed to provide for a sequentially more realistic ESS experience. For each model, there was both a right- and left-side version. The anatomy was built for the right nostril and was reflected to simulate the left nostril. The nostril (left or right) with which the subject started was determined by their handedness.

Model 1: The novice/abstract model consisted of only the skin of the face and the entrance to the nasal cavity. A 3D grid pattern replaced the sinus anatomy to provide depth of field during the three tasks: navigation, injection and dissection. Training aids were used to guide the subjects through the task. Navigation training aids consisted of virtual hoops; injection training aids consisted of virtual targets in space.

During navigation, the subjects maneuvered the endoscope through four sets of virtual hoops. The paths of the hoops represented three passes (sets two and three combined are one pass) commonly taken before the surgery begins to gain familiarity with the patient's anatomy and to allow cleaning of the areas of interest.

Injection consisted of maneuvering both the endoscope and instrumented forceps within the environment to inject five targets oriented obliquely in space. The instrumented forceps controlled a virtual needle for this task. The placement of the targets in space reflected the common areas of injection of a vasoconstrictor during a limited ethmoidectomy.

During dissection, the subjects were also required to use both the endoscope and the instrumented forceps. The task consisted of dissecting each of a series of virtual spheres with pre-selected virtual tools. The instrumented forceps represented each of the tools most commonly used in the procedure: freer, needle, bent needle, sickle knife, microdebrider, suction, straight-biting forceps, up-biting forceps, left-biting forceps and right-biting forceps.

Navigation through the four sets of hoops, injection of the five targets and dissection of each of the spheres was required for a complete score. Digitized voice audio cues were given for each hoop negotiated in navigation, for the percentage of each target injected, for percentages completed of each sphere during dissection, and for final completion of each subtask.

Model 2: The intermediate model was composed of the navigation and injection training aids from Model 1, overlaid within a virtual anatomical model of the sinus cavity. Injection and dissection followed the protocol for a limited ethmoidectomy: injection of the inferior/anterior middle turbinate, superior root of the middle turbinate and the lateral nasal wall, followed by dissection of the uncinate process, bulla ethmoidalis and posterior ethmoid cells. Labels were added for all anatomical structures with which the subject interacted.

Navigation through the four sets of hoops, injection of the five targets, medialization of the middle turbinate, dissection of the three anatomical structures, removal of two bone fragments placed in the

uncinate process and removal of three bone fragments placed in the bulla ethmoidalis were required for a complete score. The widening of the maxillary ostium was not included in the procedure due to the inability to dissect enough of the lateral part of the uncinate process for realistic viewing of the ostium. Audio cues were given for each hoop negotiated in navigation, for each target hit in injection, for each bone fragment removed and for percentages completed for each anatomical structure in dissection.

Model 3: The advanced model was composed of an anatomical model only. Subjects were expected to perform the three tasks without the training aids and to follow the protocol for a limited ethmoidectomy. Three polyps were added superior/anterior to the bulla ethmoidalis.

During navigation, the subject was required to perform the three passes in the same order as in Models 1 and 2: inferior pass along the floor of the nose to the nasopharynx, followed by a more superior pass medial to the middle turbinate towards the upper aspect of the nasopharynx and sphenoid ostium, then rolling under the middle turbinate to inspect the ostial meatal complex, and finally the superior pass medial to the root of the middle turbinate towards the sphenoethmoidal recess.

During injection, the subject was cued only by the amount of blanching (whitening) of the virtual tissue as to whether more vasoconstrictor was needed.

Dissection followed the protocol for a limited ethmoidectomy. Navigation through the three passes, injection of the areas of interest, medialization of the middle turbinate, dissection of the three anatomical structures, dissection of the three polyps, removal of two bone fragments placed in the uncinate process and removal of three bone fragments placed in the bulla ethmoidalis were required for a complete score. Audio cues were given only at the end of each of the navigation passes, for removal of bone fragments and for percentages completed in injection and dissection.

Proctoring

During each trial, a proctor with knowledge of the procedure was present; proctoring for each of the groups varied according to their familiarity with the task. To assure that all records of the trial and all subject comments were noted, a second proctor was usually present. One proctor was designated as an instructional proctor who would introduce the subject to the simulator and answer any questions during the trial. The second proctor would manage the forms, records and loading of the trials for the subject.

Non-Physician Group

Each subject was initially introduced to the simulator and informed that we were evaluating the simulator as a possible trainer for residents in Otolaryngology. A summary of the reasons for this type of surgery was given along with a brief introduction to the anatomical structures and their locations in the sinus cavity to give the subjects a feel for the dimensions of the area in which they would be working.

Subjects were then introduced to the instrumented endoscope and informed of their ability to rotate the image axially by rotating the shaft of the endoscope. They were then introduced to the instrumented forceps and informed that the forceps would be simulating the virtual needle for injection and all dissection tools. The mechanics of the forceps (open and closed) were described as simulating the plunger for the syringe during injection and opening and closing the jaws of the

dissection tools. They were then shown how the instrumented forceps would be positioned in the opposite nostril until the beginning of injection.

Subjects were given a brief verbal description of the three tasks for Model 1 (navigation, injection and dissection) and what would be required of them during the trial. They were informed that their introduction to Model 1 would be broken up across the three subtasks. A videotape of Dr. Edmond performing the trial was then started, during which the subject was allowed to step up to the mannequin and become familiar with the instrumentation, while the proctor described the task in more detail. Subjects were encouraged to ask any questions and "think aloud" during the entire procedure.

Following instructions and video for navigation, the subject independently performed the navigation task. The trial was then paused, proctoring and video for injection was given, and the injection task was performed. At that time the proctor would pull the instrumented forceps across the columella nasi into the nostril being used and place a plug in the original nostril to inhibit re-crossing of the columella nasi by the instrumented forceps during the remainder of the trial. After injection, the trial was then paused, instructions and video for dissection were provided, and the dissection task was performed.

Model 1 was the only model where this process was used and it was used only on their initial introduction to the simulator. On subsequent trials of Model 1, they were given verbal proctoring instructions only, and allowed to perform the task. Those who were introduced to Model 2 did not require breaking the trial into subtasks.

Progression to Model 2 was based on performance on Model 1. An average score of 54% was required of the subjects on Model 1 before progressing to Model 2. Since subjects in this group had no familiarity with the procedure or with paranasal sinus anatomy, Model 2 required extensive proctoring instructions on locations and anatomy to dissect during the procedure. No subjects from this group were run through Model 3 because of their inability to achieve adequate proficiency in Model 2 during the time course of the study.

Non-ENT Physician Group

Again, each subject was initially introduced to the simulator and informed that we were evaluating the simulator as a possible trainer for residents in Otolaryngology. They were encouraged to think of ways in which this type of simulator could be used in their own fields. They were then introduced to the virtual endoscope, informed of their ability to rotate the image axially by rotating the shaft of the endoscope, and of the availability of 30° and 70° scopes which could be swapped for the zero degree scope they would initially be given. The optics of the 30° and 70° scopes were explained where necessary.

Subjects were then introduced to the instrumented forceps and informed that the instrumented forceps would simulate the virtual needle for injection and all dissection tools. The mechanics of the instrumented forceps (open and closed) were described as simulating the plunger for the syringe during injection and opening and closing the jaws of the dissection tools. They were then informed of how the instrumented forceps would be positioned in the nostril opposite the one used in the trial, until the beginning of injection.

The subjects were then given a brief verbal description of the three tasks of Model 1 (navigation, injection and dissection) and what would be required of them during the trial. A video of Dr.

Edmond performing the trial was then started, while the proctor continued to describe the subtasks in more detail and what was required for completion of the trial. During this time the subject was allowed to step up to the mannequin and become familiar with the instrumentation. The "blood effects scope" (scope becoming opaque within a set time interval) was shown in the video and reasons for it were described by the proctor, along with how to relieve the problem by wiping the "scope" on the foam pad located on the mannequin's forehead.

The subject was encouraged to ask any questions and "think aloud" during the procedure. This process was repeated before their first introduction to Model 2, with the appropriate, model-specific changes. On subsequent trials of Model 1 and Model 2 they were given verbal proctoring instructions only before performing the task.

The subject's familiarity with the procedure determined the need for further instruction by the proctor. On average, this group had no familiarity with the procedure, but all had prior introduction to anatomy (during medical school) and an understanding of the reasons for the procedure. Progression to Model 2 for this group was based on performance on Model 1; an average score of 69% was required on Model 1 before progressing to Model 2. Proctoring for Model 2 required instructions on locations and anatomy to dissect during the procedure. Training aids and video of the procedure provided adequate introduction to the task for Model 1's entirety and for Model 2's navigation and injection tasks. No subjects from this group were run through Model 3, due primarily to the limited availability of these MD subjects.

ENT Staff and Residents

Again, each subject was initially introduced to the simulator and informed that we were evaluating it as a possible trainer for residents in Otolaryngology. They were introduced to the virtual endoscope, informed of their ability to rotate the image axially by rotating the shaft of the endoscope, and of the availability of 30° and 70° scopes which could be swapped for the zero degree scope they would initially be given.

Subjects were then introduced to the instrumented forceps and informed that they would simulate the virtual needle for injection and all dissection tools. The mechanics of the instrumented forceps (open and closed) were described as simulating the plunger for the syringe during injection and opening and closing the jaws of the dissection tools. They were then informed of how the instrumented forceps would be positioned in the nostril opposite the one used in the trial until the beginning of injection.

The subjects were then given a brief verbal description of the three tasks of Model 1 and what would be required of them during the trial. The video of Dr. Edmond performing the trial was then started, while the proctor continued to describe the subtasks in more detail and what was required for completion of the trial. During this time, the subject was allowed to step up to the mannequin and become familiar with the instrumentation.

The "blood effects scope" was shown in the video and reasons for it were described by the proctor, along with how to relieve the problem by wiping the scope on the foam pad located on the mannequin's forehead. Subjects were encouraged to ask any questions and "think aloud" during the procedure. On subsequent trials they were given verbal proctoring instructions only (with the appropriate, model-specific changes), and allowed to perform the task.

The subject's familiarity with the procedure determined the need for further instruction by the proctor. Typically, the staff otolaryngologists needed no further instruction on the procedure for the remainder of the session, except for the need to be shown the active areas for dissection of the uncinate process, bulla ethmoidalis and posterior ethmoid cells within the virtual model. In general, the staff ENT subjects ran through all three model levels.

Similarly, the ENT residents needed no further instruction for Model 1. For Model 2, however, more detailed instructions were sometimes needed during dissection on what anatomy to dissect and where the active dissection areas were located within the anatomy. In Model 3 more detailed instructions were also needed during navigation on the order of passes to perform and where the active dissection areas were located within the anatomy. All residents were run through Model 1-right, Model 2-right, Model 3-right, Model 3-left and Model 2-left.

User Performance Criteria

The scoring algorithm for Version 1.2 takes into consideration three major performance measures for endoscopic sinus surgery: accuracy, completeness and time. The overall trial score is calculated as:

$$(navigation\ score + injection\ score + dissection\ score) / 3$$

Subtask scores are calculated as:

$$subtask\ score = accuracy * optimal\ time / completed\ time$$

The scoring algorithm used for the evaluation of this phase of the project took into account the most important skills needed to perform sinus surgery, as well as the level of difficulty of the model. In an attempt to normalize across model conditions, the following optimal times (in seconds) were used in this scoring equation:

Navigation: advanced=97, intermediate=97, novice=97

Injection: advanced=90, intermediate=165, novice=90

Dissection: advanced=815, intermediate=635, novice=165

These times were derived from the approximate performance times for the project's lead otolaryngology advisers. If a subject performed the subtask in less than the optimal time, then their score was equal to their accuracy on that subtask.

Navigation accuracy was based on the percentage of hoops negotiated (with the hoops in the advanced model rendered invisibly). Injection accuracy scores were based on the ratio of the percentage of each target injected to a criterion percentage for that object: 100% for the graphical targets, 25% for the middle turbinate, and 10% for the nasal wall. Similarly, dissection accuracy was based on a criterion dissection percentage for each dissectable object (markers, polyps, uncinate, ethmoid cells, ethmoid bulla, maxillary ostium, and bone fragments).

3.2 Results

3.2.1 Non-Physician Evaluation

Although not the target domain audience for this simulator, the non-physician group gave us an opportunity to look at the baseline difficulty of the simulator for domain-naive users and to further

work out requirements for instructional presentation, proctoring, and pacing of the "curriculum" (after initial "shake down" and protocol development by the project staff). Since the novice model did not require interaction with the complex paranasal sinus anatomy or detailed knowledge of the surgical procedure, it was felt that this group should be able to complete those trials.

The inherent difficulty of the task for inexperienced users is evidenced by subject attrition and by their initial trial scores. Indeed, complete trial data are available for only nine of the 12 subjects in this group. Of the three lost to attrition, one terminated the session due to disorientation and discomfort with visual interface, and two were unable to complete even the navigation task during the time period available for testing. The primary difficulty observed with these three subjects was an inability to adapt to the psychomotor demands of the interface; that is, they were not able to acquire the basic skill necessary to control the positioning of the virtual endoscope within the model.

Of the nine remaining subjects in this group, five had had considerable experience with videogames and three with commercial flight simulators. Thus the trials scores for this group may represent the high end of non-physician users and should not be taken as a sample from the general non-physician population.

Novice Model Performance

Still, despite attrition of the low-end performers and the unusual prior experience of the remaining subjects, the non-physician group performed significantly worse than the ENT group on their initial novice level trials (as can be seen graphically in a later section).

Unpaired student's t comparisons with the ENT group revealed significantly:

lower overall trial scores (non-physician mean = 45.9, ENT mean = 65.1, $t = 2.87$, $p = .0098$),

longer overall trial times (non-physician mean = 1012 sec, ENT mean = 692 sec, $t = 2.14$, $p = .0458$),

lower navigation scores (non-physician mean = 47.1, ENT mean = 69.4, $t = 2.39$, $p = .0276$),

longer navigation times (non-physician mean = 239 sec, ENT mean = 146 sec, $t = 2.52$, $p = .0209$), and

lower injection scores (non-physician mean = 55.3, ENT mean = 81.5, $t = 2.46$, $p = .0235$)

Injection times, while not significantly longer, did approach significance (non-physician mean = 257 sec, ENT mean = 117 sec, $t = 1.96$, $p = .0649$). Surprisingly, while dissection scores and dissection times were slightly worse for the non-physician group, these differences were not significant. This relatively poor performance by the ENT group on their initial dissection trial is discussed further below.

Practice Effect

Six of the 12 subjects in this group had complete trial scores for at least two novice trials. Students' t comparisons of their first and second novice trials showed that their second trial resulted in significantly:

Higher overall trial scores (trial 1 mean = 46.7, trial 2 mean = 69.5, $t = 2.33$, $p = .0423$),

Higher injection scores (trial 1 mean = 53.8, trial 2 mean = 86.7, $t = 2.22$, $p = .0500$),

Shorter dissection times (trial 1 mean = 492 sec, trial 2 mean = 328 sec, t = 2.39, p = .0382), and

Higher dissection scores (trial 1 mean = 35.8, trial 2 mean = 51.8, t = 2.55, p = .0287).

Total trial times, navigation times and scores, and injection times all changed in the expected direction (that is, they improved across trials), but none of these improvements was statistically significant. It appears that, for this non-physician group, the primary challenge may have been mastering the endoscope positioning.

Intermediate Model Performance

First-time intermediate level scores were acquired for only 3 of the subjects in the non-physician group. Despite this small N, unpaired student's t comparisons with the ENT group revealed significantly

Lower overall trial scores (non-physician mean = 53.7, ENT mean = 76.7, t = 3.53, p = .0041),

Longer overall injection times (non-physician mean = 359 sec, ENT mean = 132 sec, t = 6.91, p = .0001), and

Lower injection scores (non-physician mean = 47.1, ENT mean = 69.4, t = 2.39, p = .0276).

Overall trial times, while not significantly longer, did approach significance (non-physician mean = 1532 sec, ENT mean = 1215 sec, t = 1.79, p = .098), as did navigation times (non-physician mean = 199 sec, ENT mean = 138 sec, t = 2.08, p = .0592) and navigation scores (non-physician mean = 48.0, ENT mean = 73.7, t = 1.99, p = .0698). Again, no difference was found between the two groups in initial dissection times and dissection scores on the intermediate model.

The experiential advantage of the ENTs is perhaps most telling in their superior injection task performance. As will be seen below in examining trends within the ENT group, ability to perform efficient injections may by the hallmark of the accomplished surgeon, much more so than the ability to perform efficient dissection (at least as indicated by simulator performance).

3.2.2 Non-ENT Physician Evaluation

The primary objectives of the non-ENT physician evaluations were to provide a medically trained comparison and "shakedown" group and to explore the perspectives of other medical specialties regarding additional potential applications for this sort of simulation training. In particular, we were interested in applications which might make use of the integrated approach and specific components incorporated into the Madigan ESS simulator.

Novice Model Performance

Novice performance measures for the non-ENT MD group were very similar to those for the experienced ENT group (as summarized graphically below in the ENT analysis section). While there were no statistically significant differences between these two groups, it should be noted that the mean differences for all of the performance measures were in the direction we had expected (that is, the mean performance measures were consistently better for the ENT group).

This finding may be due to the considerably broad prior medical and interface experience for all of the subjects in this group. Most of the subjects in this group have been involved over the years in

developing or testing novel interface devices for medical tasks, and several had previous experience test-driving similar medical simulators.

Perhaps the greatest mitigating factor, however, is the extensive experience that two of these four subjects had acquired as videoendoscopic surgeons. This experience provided them with a background comparable to the ENT group in basic endoscopic psychomotor skills, as well as in general procedural knowledge and confidence.

Although there were no statistically significant differences in any performance measures between the non-ENT MDs and the non-physician subjects, it was apparent that they were much more comfortable with the experimental task requirements. This finding (and the nature of the questions asked during the session) suggests the value of a general medical perspective in assuring confidence with this sort of procedural simulator.

Intermediate Model Performance

Three of the non-ENT MD subjects also tried the intermediate model. Comparison of the non-ENT MDs with the ENTs on their first trial on the intermediate model reveals an interesting finding. While there was no significant difference between the groups in overall score and trial time, the non-ENTs did notably better than the ENTs on the dissection subtask. Dissection scores were significantly better for the non-ENTs (non-ENT mean = 84.0, ENT mean = 63.1, $t = 2.439$, $p = .0312$), which appears to be due primarily to their faster times on that task (non-ENT mean = 662 sec, ENT mean = 880 sec, $t = 1.99$, $p = .0692$), a non-significant but clearly suggestive finding.

Looking at individual scores, we note that this effect is due to the relatively fast dissection times for the two videoendoscopic surgeons. While we would expect that the ENT group would be superior to all other groups on this task, the extensive background in similar procedures appears to have prepared the general surgeons well for this task.

Related Medical and Surgical Applications

Response by the non-ENT physician group was uniformly positive. Each of them suggested additional applications, both within and outside of their particular specialties, that would be amenable to a similar simulation approach. These suggested applications included:

- Neurosurgery: approaching the pituitary gland through the sphenoid sinus
- Anesthesiology: intubation, bronchioscopy
- Videoendoscopic surgery: cholecystectomy, bladder, joints, throat, chest procedures
- Cardiology: cannulization, thoracoscopic surgery
- Gastroenterology: endoscopic procedures
- Radiology: fluoroscopy, intrusive ultrasound procedures (e.g., transesophageal echocardiography)

In general, procedures that use endoscopes or probes to explore internal structure and to perform manual procedures should be amenable to this simulation approach. Several of the physicians in this group indicated that they would like to see work proceed in that direction and that there would be support for this development from the leaders within their specialties.

3.2.3 Staff and Resident ENT Evaluations

Simulator performance measures were acquired on 53 separate trials for the 12 ENT subjects between 5/13/97 and 8/12/97 (23 trials run at HITL, and 30 trials run at MAMC). The number of trials acquired for each subject ranged from 2 to 12, with all subjects being tested (minimally) on both the novice and the intermediate model.

Initial Novice Model Performance

Figure 4 shows the distribution of trial scores on the initial novice trials for the 12 ENT subjects.

To examine the degree to which prior OR experience might contribute to these initial score differences, we calculated the Pearson product-moment correlation coefficients ("r") across the primary performance measures (trial time and trial score) and the primary experience measures (age, years of ESS training, and approximate number of actual ESS procedures performed. A matrix of these correlations appears in Table 1 (critical r = .6021 for probability p < .05, degrees of freedom df = 9).

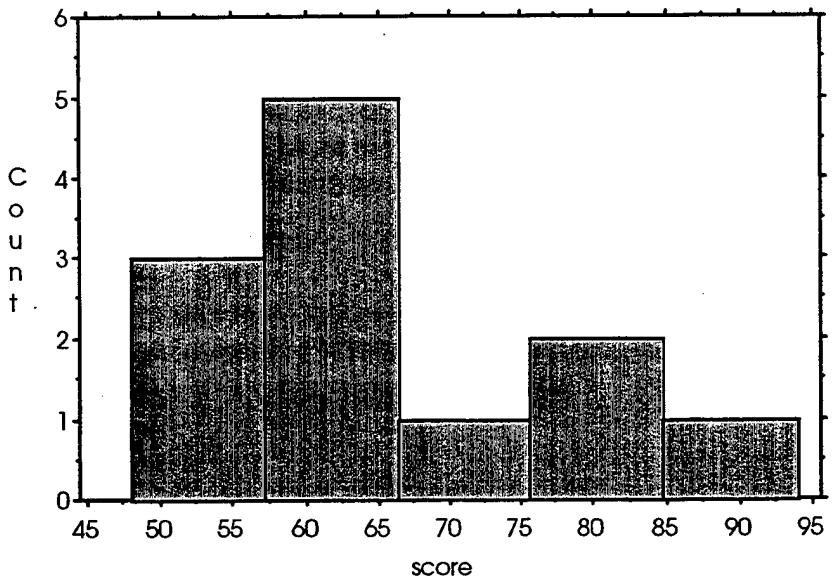


Figure 4. Frequency distribution of overall scores on initial trial on novice model by subjects in ENT group.

As can be seen, the best predictor of novice trial time from among the surgical experience measures is the number of actual ESS cases performed (r = -.652), with trial time decreasing significantly with surgical experience. For trial score, the findings are less conclusive, although the best experiential predictor is again the number of ESS cases performed (r = .526). While age is naturally correlated with ESS experience and training, age alone does not appear to be a significant predictor of simulator performance for these ENT subjects.

Table 1. Correlation matrix showing relationships among ESS experience measures and overall performance measures on the novice model for 12 ENT subjects.

	Score	ESS perf	Years_tr	Age	Trialtime
Score	1				
ESS performed	.526	1			
Years_training	.38	.923	1		
Age	.236	.662	.713	1	
Trialtime	-.966	-.652	-.514	-.33	1

Note: 1 case deleted with missing values.

In general, we see that trial score on the initial novice simulator trial is indeed positively correlated with prior ESS experience. This finding suggests that the simulator provides a valid reflection of the skills acquired in ESS procedures.

Subtask Performance on Initial Novice Trial

Not surprisingly, overall trial scores are, with the sole exception of injection time, significantly correlated with subtask scores and times, as shown in Table 2 (critical r = .5760 for $p < .05$, df 10). Overall trial times are similarly related to subtask performance measures, although by far the strongest predictor of overall trial time is performance on the dissection task (r = .897 for dissection time and -.918 for dissection score).

Table 2. Correlation matrix showing relationships among ESS procedures previously performed and subtask performance measures on novice model for 12 ENT subjects.

	Score	Trialtime	Navtime	Navscore	Initime	Injscore	Disstime	Disscore
Score	1							
Trialtime	-.965	1						
Navtime	-.587	.469	1					
Navscore	.68	-.573	-.97	1				
Initime	-.531	.508	-.109	.092	1			
Injscore	.684	-.667	.016	.033	-.957	1		
Disstime	-.784	.897	.189	-.342	.3	-.476	1	
Disscore	.856	-.918	-.275	.413	-.352	.524	-.964	1
ESS Perf.	.504	-.614	-.245	.227	-.425	.428	-.526	.471

As before, prior ESS experience is predictive of overall trial time (r = -.614), and, although its relationship to each of the subtask measures is consistent with simulator validity, none of these correlations are statistically significant.

Novice Model Performance Across ENT Groups

Figure 5 shows the breakdown of first-time novice (abstract) model scores for this group. The linear relationship between overall novice trial score and year of residency is apparent from this mapping. It is interesting to note that the R5 residents appear to have higher scores on the novice model than

the experienced ENT staff subjects. This could be due to a number of factors, including the relatively high number of procedures performed routinely by the R5s.

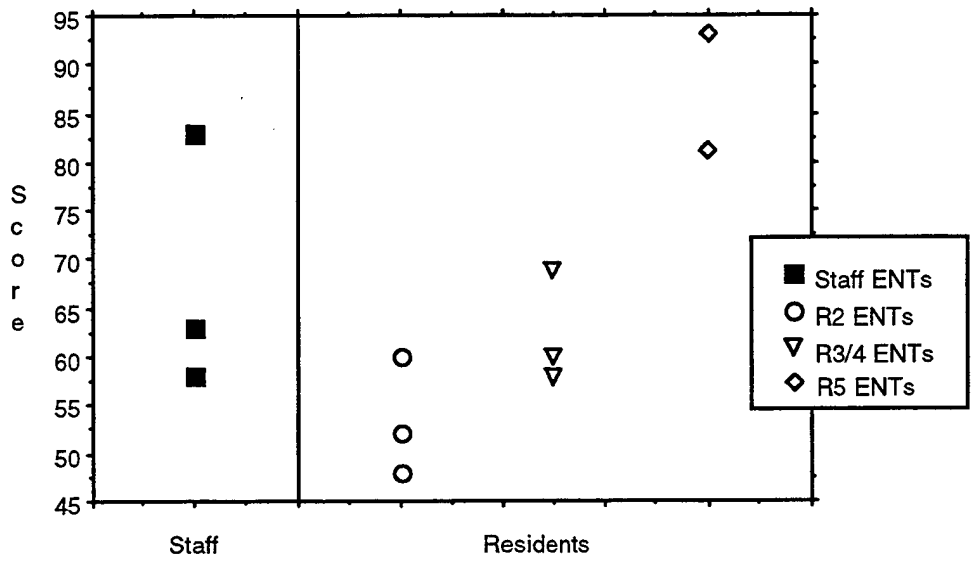


Figure 5. Overall scores for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

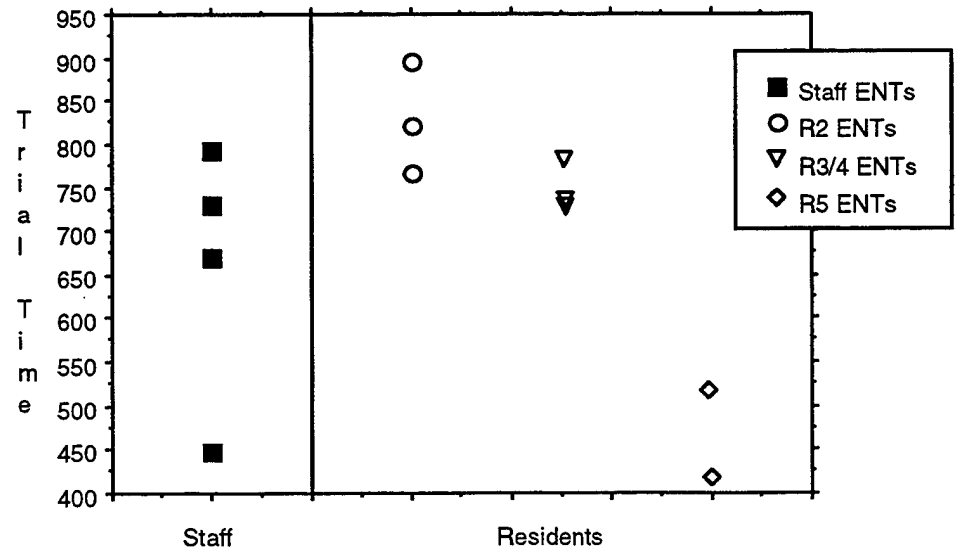


Figure 6. Overall trial times for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

Similarly, it can be seen in Figure 6 that overall trial times for the initial novice trials fall off as expected with year of residency. Both of these findings provide strong evidence for the validity of the simulator for the ESS task, even when the model is abstract.

Subtask Times By Year of Residency

A breakdown of trial times by subtask is shown for the range of ENT subjects in Figures 7-9.

Figure 7. Navigation times for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

While resident subtask times generally decrease with year of residency, dissection times indicate a nonlinear trend, with residents in the middle years of training taking longer to dissect than the R5 residents (who have had considerably more experience). This effect may perhaps be due to the degree of caution observed by the R3s and R4s as they become aware of the procedural risks during dissection but do not yet have their instrument control skills well honed.

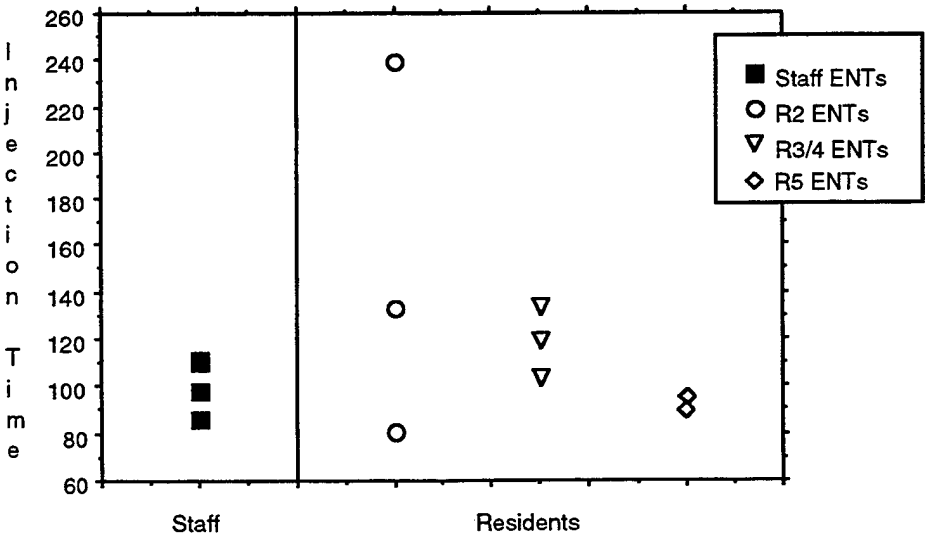


Figure 8. Injection times for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

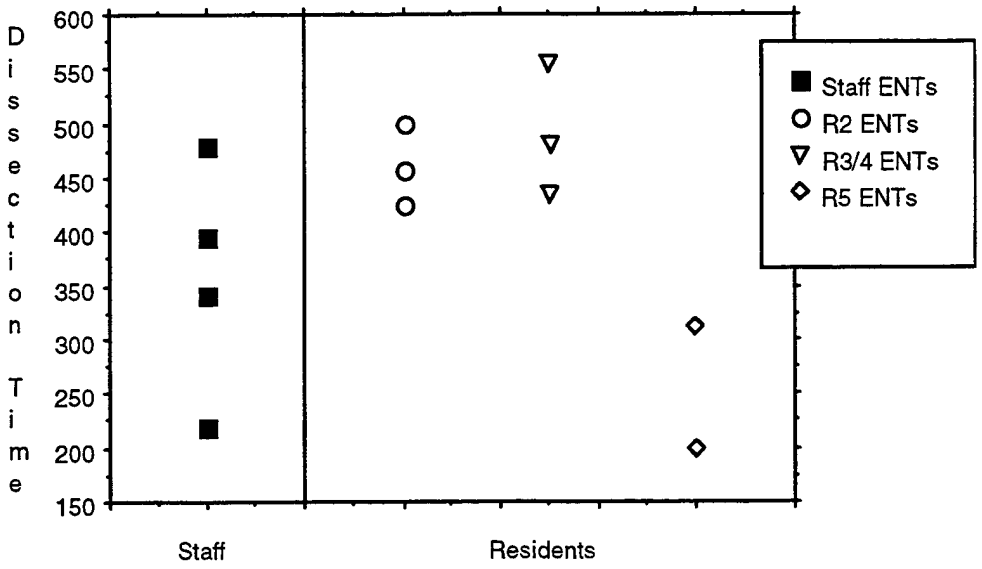


Figure 9. Dissection times for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

These subtask times for the staff ENTs suggest that injection skill is well learned by this time, while the finding of relatively more variability in navigation and dissection times may reflect differences in style, with some experienced surgeons remaining (appropriately) more cautious and perhaps more attentive to the potential hazards of making a mistake.

Subtask Scores By Year of Residency

A similar breakdown for subtask scores (shown in Figures 10-12) mimics the trends for subtask time.

Figure 10. Navigation scores for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

Scores on each subtask generally increase with year of residency, with the exception of R3s and R4s achieving slightly lower scores for dissection than their junior and senior colleagues. Injection scores for R5s are comparable with staff ENTs, while R5 navigation and dissection scores appear to be superior.

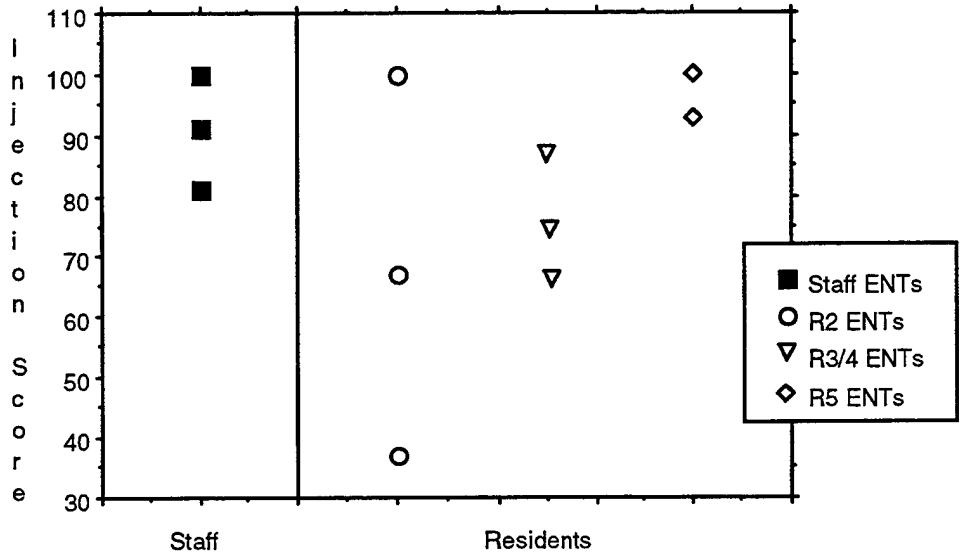


Figure 11. Injection scores for first trial on novice model for ENT staff and ENT residents, plotted by year of residency.

Figure 12. Dissection scores for first trial on novice model for ENT staff and ENT residents.

Novice Model Performance Across Subject Groups

Figure 13 shows the distribution on overall scores on the first novice trial for all three subject groups, while Figure 14 shows the same for overall trial times.

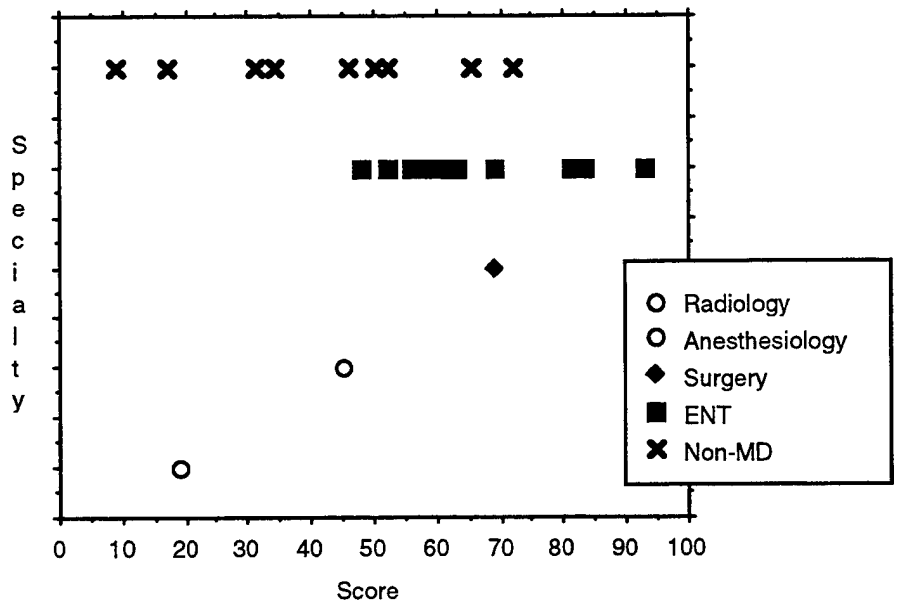


Figure 13. Overall scores for first trial on novice model for the non-physician group, the non-ENT physician subjects (representing three specialties), and the ENT group.

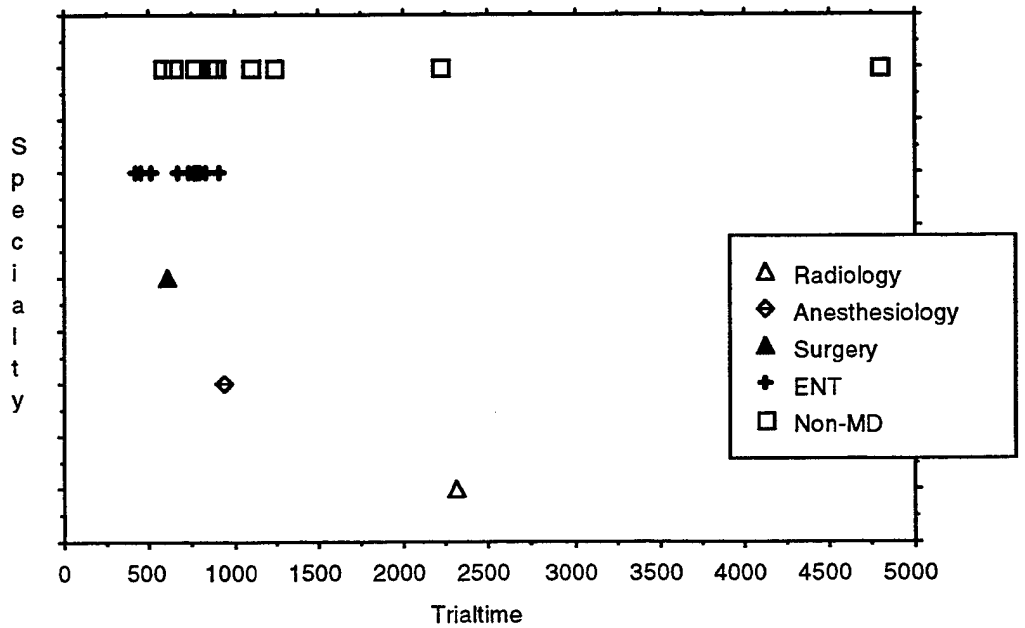


Figure 14. Overall trial times for first trial on novice model for the non-physician subject group, the non-ENT physician subjects (representing three specialties), and the ENT group.

The non-physician group is clearly less skilled than the ENT group (as discussed above), while the non-ENT physicians demonstrated more variable performance. Note the two videoendoscopic surgeons had identical overall scores on their novice trials (and overall times that were essentially the same, as well), and that their performance was comparable to the average ENT subject. The anesthesiologist also did surprisingly well, due perhaps to that subject's extensive clinical experience performing image-guided and vital sign-guided procedures which require new psychomotor skills.

Initial Intermediate Model Performance

Figure 15 shows the distribution of trial scores on the initial intermediate trials for the 12 ENT subjects. (Note that the first intermediate trial for one of these subject was terminated after the navigation phase and is consequently not included here.)

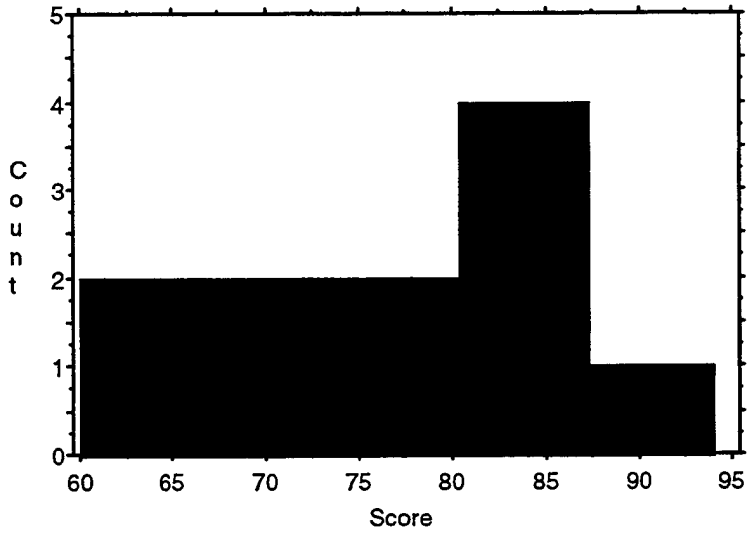


Figure 15. Frequency distribution of overall scores on initial trial on the intermediate model by subjects in the ENT group.

Although we might expect a positive relationship between ESS experience and novice model performance, we would expect that OR experience would be especially predictive of performance when the sinus anatomy serves as the model. A matrix of these correlations appears in Table 3 (critical r = .6319 for $p < .05$, df 8).

In contrast to the initial novice scores, these results indicate that the best predictor of initial intermediate trial time (from among the surgical experience measures) is subject age (r = -.475), but this correlation is not statistically significant. For trial score, the findings are also inconclusive, with the best experiential predictors being subject age (.581) and number of ESS cases performed (r = .555).

Table 3. Correlation matrix showing relationships among ESS experience measures and overall performance measures on the intermediate model for the 12 ENT subjects.

	Score	ESS perf	Years_tr	Age	Trialtime
Score	1				
ESS performed	.555	1			
Years_training	.356	.931	1		
Age	.581	.667	.68	1	
Trialtime	-.795	-.144	-.014	-.475	1

Note: 1 case deleted with missing values.

In general, we see that initial performance on the intermediate model is indeed positively correlated with prior ESS experience, but the relationship is not as strong as for initial novice model performance. Table 4 attempts to shed light on this unexpected finding by looking more closely at experiential correlates of performance on procedural subtasks for the initial intermediate trial (critical $r = .6319$ for $p < .05$, df 8).

Table 4. Correlation matrix showing relationships among ESS experience measures and subtask performance measures on the intermediate model for the 12 ENT subjects.

	ESS perf...	Years_t...	Age	Navtime	Navscore	Injtime	Injscore	Disstime
ESS perf...	1							
Years_tr...	.931	1						
Age	.667	.68	1					
Navtime	-.569	-.314	-.386	1				
Navscore	.509	.288	.36	-.971	1			
Injtime	-.869	-.847	-.624	.435	-.413	1		
Injscore	.859	.798	.525	-.476	.446	-.967	1	
Disstime	.199	.229	-.428	.191	-.224	-.275	.362	1
Disscore	-.059	-.144	.462	-.354	.381	.186	-.226	-.967

Note: 1 case deleted with missing values.

It appears from Table 4 that prior ESS experience is indeed a strong predictor of performance on the initial intermediate injection task ($r = -.859$ for injection time and .859 for injection score) and a slightly weaker predictor of performance on the initial intermediate navigation task ($r = -.569$ for navigation time and .509 for navigation score).

Performance on the initial intermediate *dissection* task, however, is actually the reverse of our predicted effect: dissection times are slightly longer for more experienced surgeons on their first encounter with the intermediate model, and dissection scores are slightly lower.

These findings are deserving of further study. One possible explanation might be that there is significant negative transfer to the simulated dissection task due to more extensive experience with

the real instruments and real anatomical dissection. Comments from experienced ESS surgeons regarding the difficulty of the dissection task support this notion.

Intermediate Model Performance Across ENT Groups

As shown in Figures 16 and 17, scores on the initial intermediate trial generally improved with year of residency. Overall trial times, on the other hand, appear to have remained relatively constant, but perhaps less variable, over residency training year.

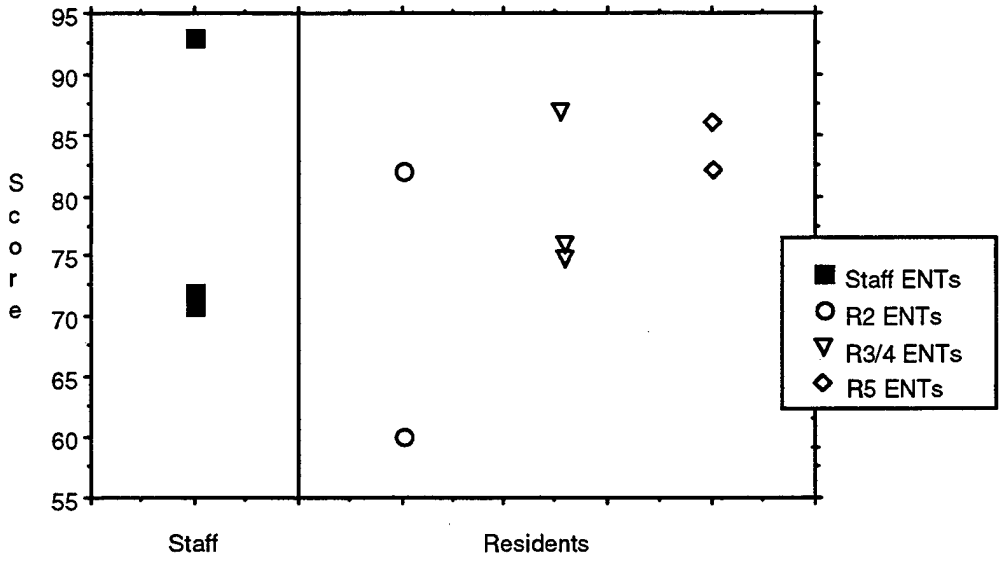


Figure 16. Overall scores for first trial on intermediate model for ENT staff and ENT residents, plotted by year of residency.

While intermediate trial times might be expected to be lower than those for the residents, their real world experience with the procedure may actually make them more cautious, as noted above. The experienced sinus surgeon knows, for example, that if he traumatizes the septum or middle turbinate during the navigation phase, it will create bleeding that will affect the rest of the surgical procedure.

Figure 17. Overall times for first trial on intermediate model for ENT staff and ENT residents.

Intermediate Model Performance Across Subject Groups

Overall times and scores for initial intermediate model trials are broken down by specialty in Figures 18 and 19. As expected, the ENT group performed better on the anatomical model than did the non-physician group.

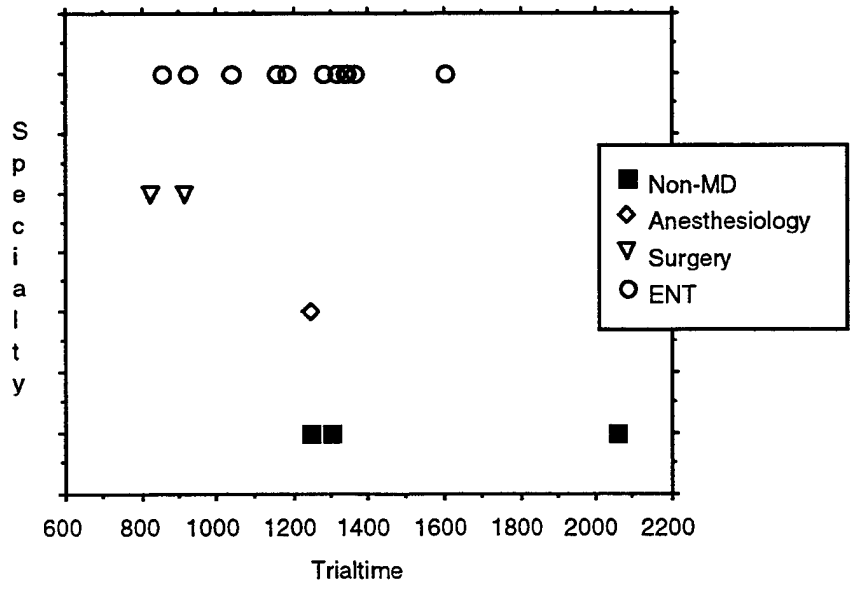


Figure 18. Overall trial times for first trial on intermediate model for the non-physician group, the non-ENT physician subjects (representing three specialties), and the ENT group.

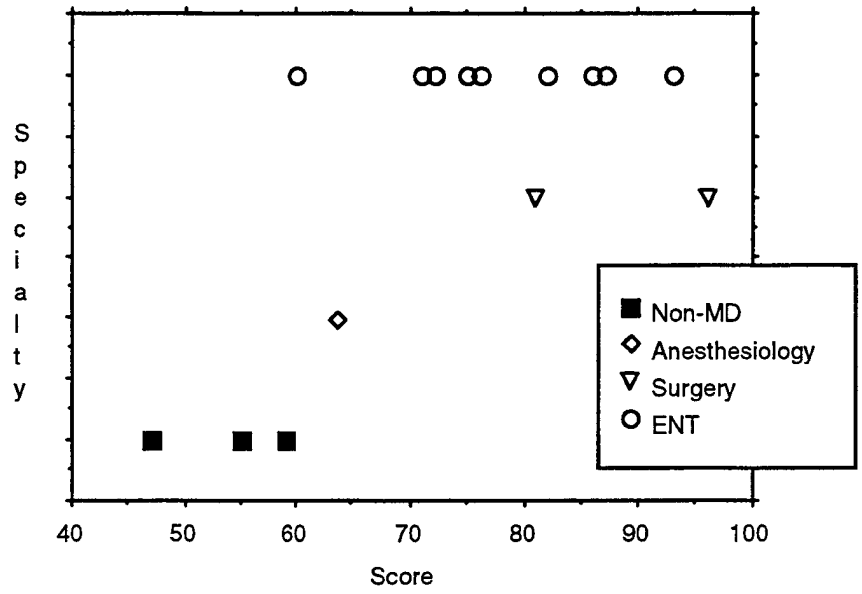


Figure 19. Overall scores for first trial on intermediate model for the non-physician group, the non-ENT physician subjects (representing three specialties), and the ENT group.

While the trial time difference between the ENT and non-physician groups was not statistically significant, the trial score difference was significant (as summarized in the table below). This finding again suggests that ESS experience is predictive of simulator performance, thus providing evidence for the validity of the system for ESS training.

Unpaired t-Test X 1 : specialty Y 1 : score

DF:	Unpaired t Value:	Prob. (2-tail):
12	-3.533	.0041

Group:	Count:	Mean:	Std. Dev.:	Std. Error:
nonMD	3	53.667	6.11	3.528
ENT	11	76.727	10.631	3.205

Figures 18 and 19 also show that the non-ENT physicians in this sample had scores that were comparable to the ENT group. (Note that the radiologist from the novice trial comparisons above was not tested on the intermediate or advanced models.) This is not surprising, given that these subjects were videoendoscopic surgeons who typically perform more endoscopic procedures on a regular basis than do ENT surgeons.

General videoendoscopic procedures may also be more challenging from a psychomotor perspective. In addition to navigation, injection and dissection, their procedures may require retracting, cautery, cutting, suturing and true dissection, with the reflection of tissues away from the area of interest. Furthermore, they perform these task in a more bi-dexterous fashion; the ENT surgeon uses both

hands, but usually one at a time. Finally, the videoendoscopic surgeon's psychomotor abilities may be challenged more during their procedures, because the endoscope and instruments are usually not coaxial.

Initial Advanced Model Performance

Advanced Model Performance Across ENT Groups

Figures 20 and 21 show the overall scores and trial times for the first advanced trial by subjects in the ENT group. Note that two of the staff subjects did not attempt the advanced model.

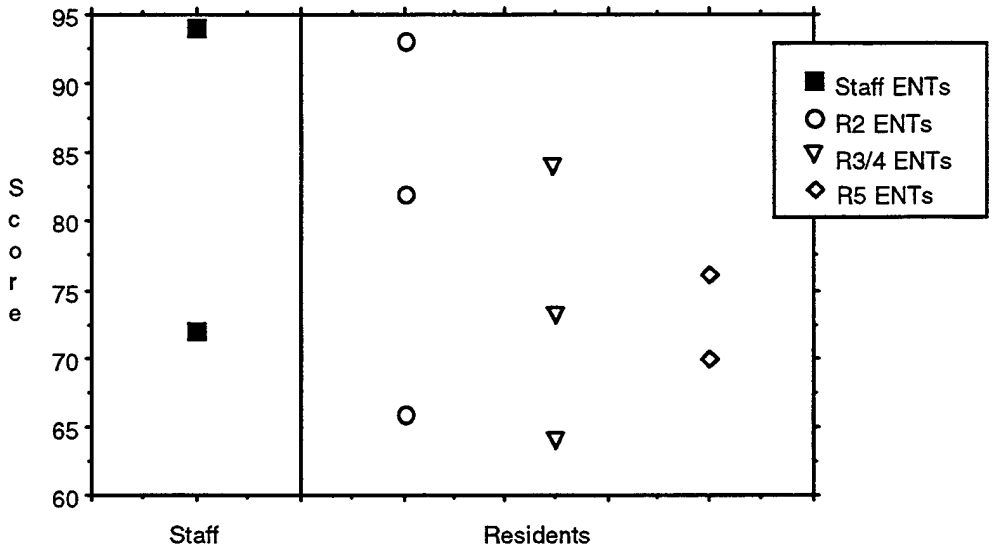


Figure 20. Overall trial scores for first trial on advanced model for ENT staff and ENT residents, plotted by year of residency.

Surprisingly, initial performance on the advanced model revealed a tendency for the more senior residents to perform at about the same speed as the staff ENT subjects but with slightly lower overall scores. This may reflect the ability of the more experienced surgeons to perform maneuvers with a higher degree of accuracy.

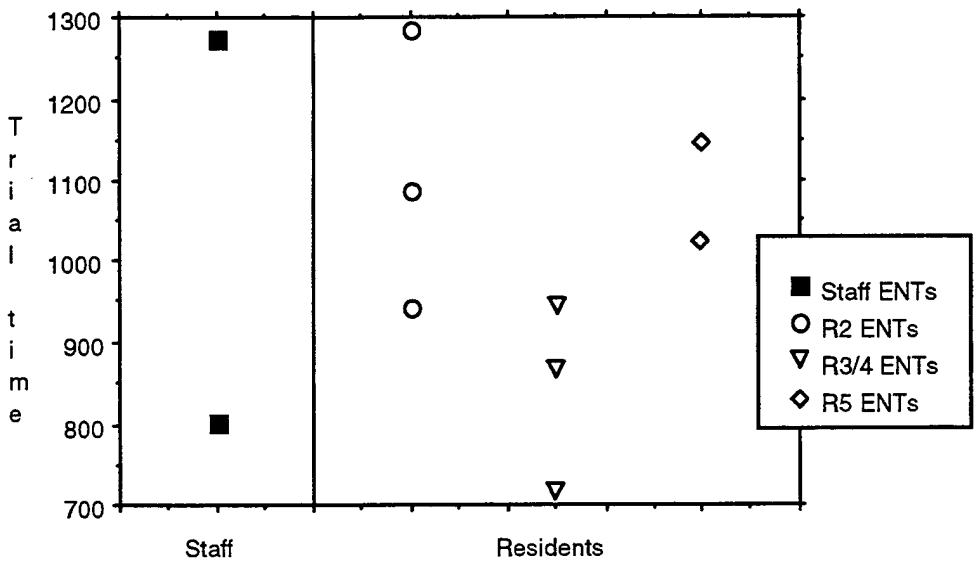


Figure 21. Overall trial times for first trial on advanced model for ENT staff and ENT residents.

While not a strictly linear relationship across years, the R3 and R4s had shorter trial times on their first advanced trial, but the R4s also had lower scores on those trials, indicating that their accuracy was lower.

Figure 22. Injection scores for first trial on advanced model for ENT staff and ENT residents, plotted by year of residency.

While overall time and score for staff ENTs did not appear to differ systematically from the resident times and scores on initial advanced model trials, their performance on the *injection* subtask appeared to be superior to the resident group (as shown in Figures 22 and 23). Similar differential performance was not seen for the navigation and dissection subtasks.

Figure 23. Injection times for first trial on the advanced model for ENT staff and ENT residents, plotted by year of residency.

Although navigation and dissection may vary with individual care and priorities, the data suggest that injection efficiency may be a hallmark of the experienced sinus surgeon. This finding should be followed up and verified in future evaluation studies.

3.2.4 Asymptotic Performance

While extensive learning curve data are not available, repeated measures on the steady-state system (version 1.2) are available for our two primary evaluation proctors (CE, an ESS surgeon, and CA, an engineering student).

Given that these two subjects had each tested the simulator in various degrees of development approximately 30-40 times over a 6-8 month period, their later scores may provide an estimate of asymptotic performance on the simulator.

ENT Steady-State Performance

Simulator performance scores were analyzed for the last 11 completed steady-state trials by the experienced ENT proctor. As can be seen in Figure 24, steady state trial times for the novice model (mean = 259 seconds, s.d. = 15.9) were lower than those for the intermediate and advanced models (combined mean = 512 seconds, s.d. = 57.1). The similarity between trials times on the intermediate and advanced models may suggest that the two tasks are comparable for the highly experienced subject and, further, that the intermediate model training aids are no longer necessary for this subject.

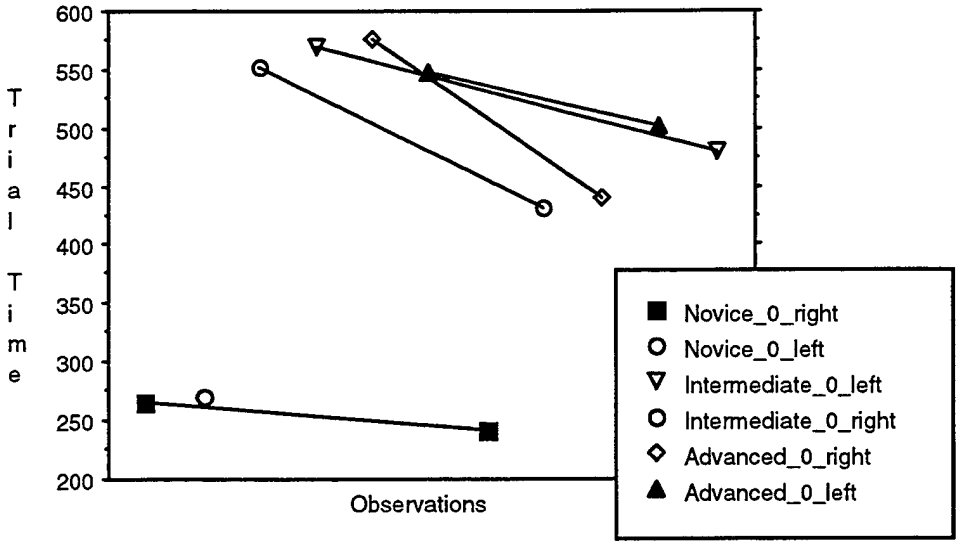


Figure 24. Asymptotic overall trial times on each model for the experienced ENT proctor. Times are plotted in order of trial presentation.

It also appears from this figure that trial times for each model are consistently lower in the last trial than in the previous trial, suggesting that these trials times may, in fact, *not* represent steady state performance. An examination of overall scores for these trials (see Figure 25) reveals, however, that for at least some of these conditions the decrease in overall trial time for these later trials came at the cost of trial score. It should be noted that, since this subject achieved the minimum required time on all subtask trials, these trial scores precisely reflect a decrement in performance *accuracy*.

Given the better trial score for the first samples for each model condition, we may tentatively treat the trial times for those first samples as more representative of optimal performance.

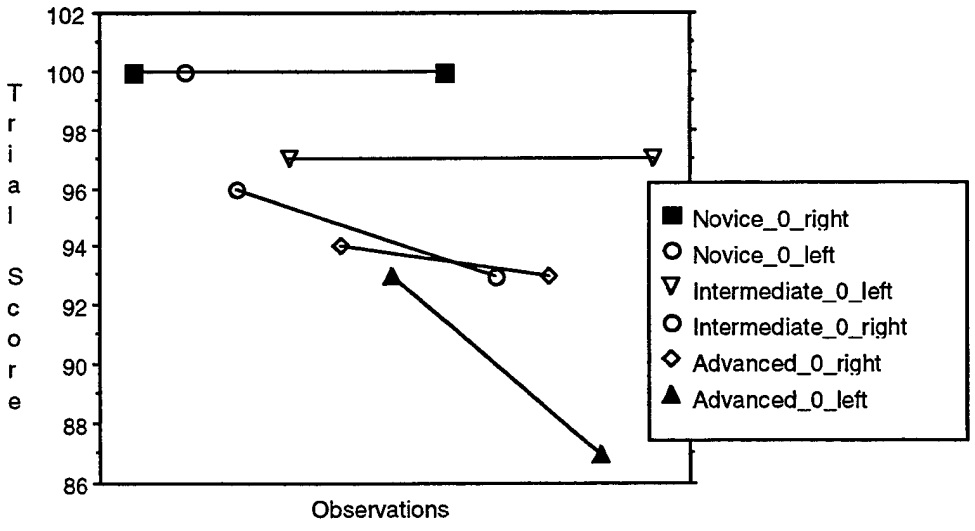


Figure 25. Asymptotic overall trial scores on each model for the experienced ENT proctor. Scores are plotted in order of trial presentation.

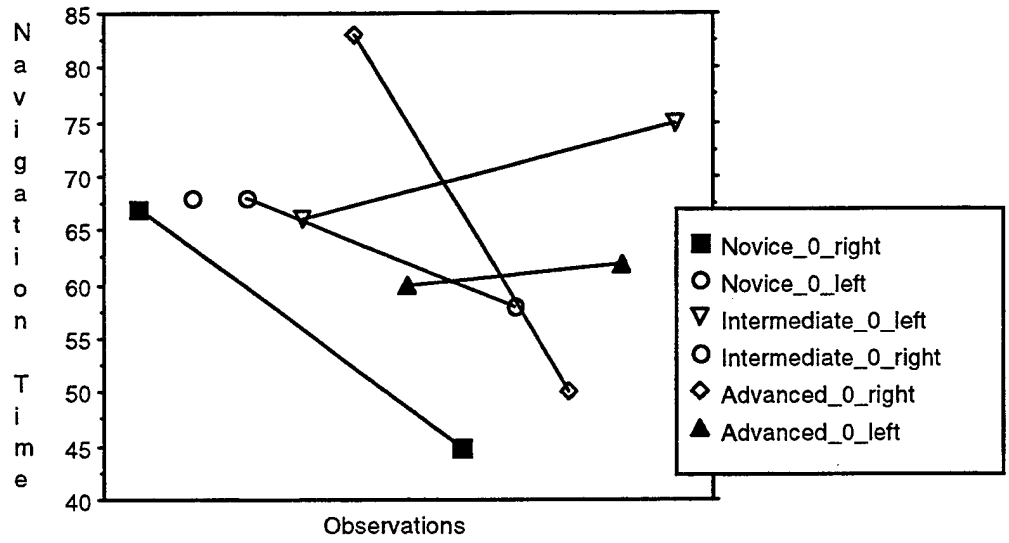


Figure 26. Asymptotic navigation times on each model for the experienced ENT proctor. Times are plotted in order of trial presentation.

It may also be instructive to look at asymptotic performance for the three subtasks for this highly experienced ENT subject. In Figures 26-28 we present the subtask times for this same set of trials. As can be seen from these figures, the systematic decrease in overall trial time for intermediate and advanced model (shown in Figure 24) appears to be due primarily to a systematic decrease in completion time for the dissection subtask, while navigation and injection times appear to vary more randomly across these temporal samples.

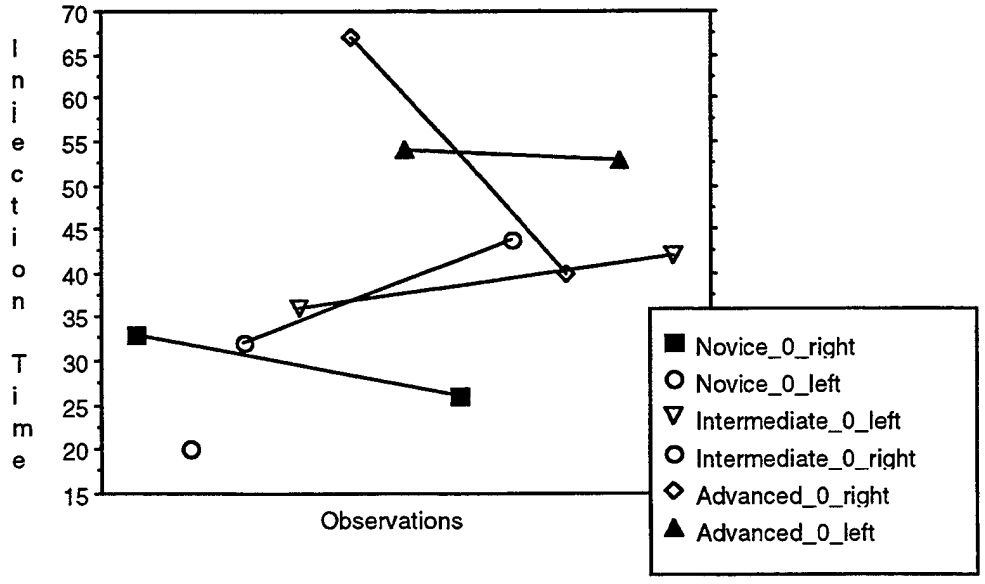


Figure 27. Asymptotic injection times on each model for the experienced ENT proctor. Times are plotted in order of trial presentation.

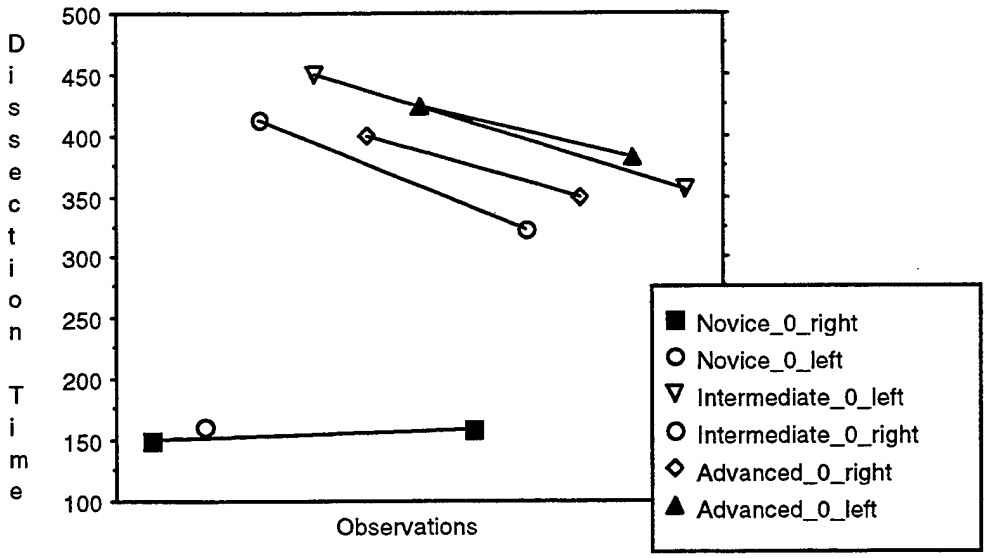


Figure 28. Asymptotic dissection times on each model for the experienced ENT proctor. Times are plotted in order of trial presentation.

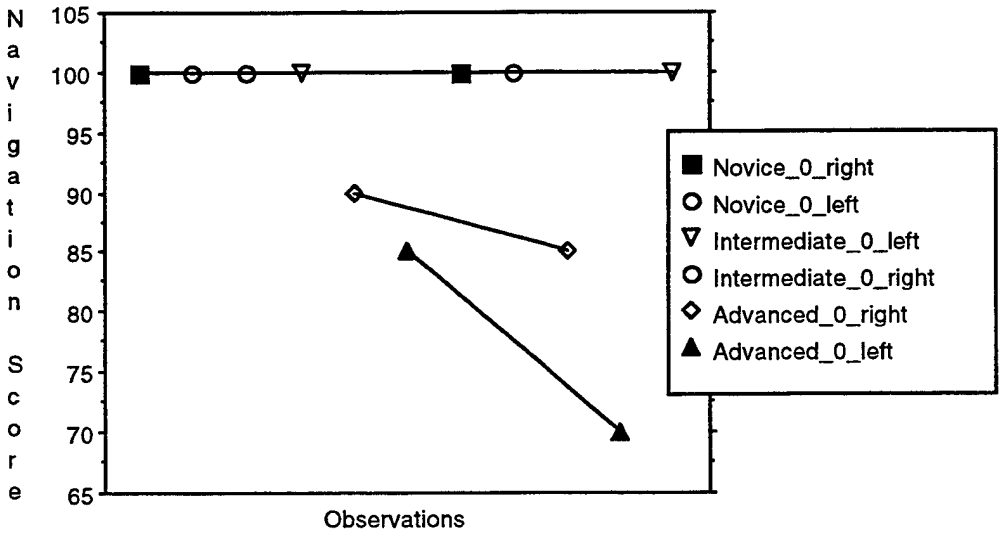


Figure 29. Asymptotic navigation scores on each model for the experienced ENT proctor. Scores are plotted in order of trial presentation.

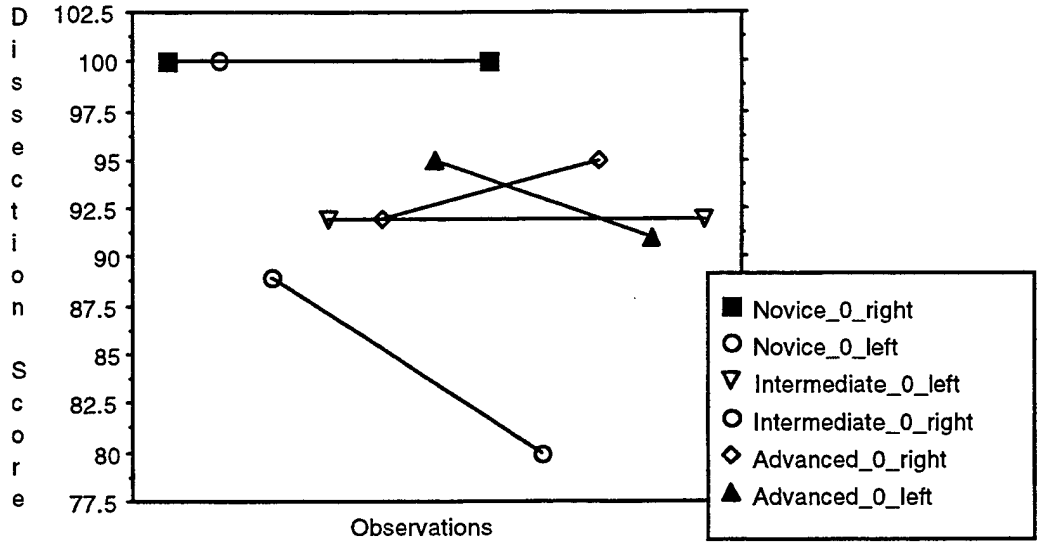


Figure 30. Asymptotic dissection scores on each model for the experienced ENT proctor. Scores are plotted in order of trial presentation.

Similarly, examination of Figures 29 and 30 suggests that the overall decrease in trial score for the intermediate and advanced models for this experienced subject are due to decreases in navigation score for the advanced model condition and a decrease in dissection score for one of the intermediate models (intermediate 0 right). Injection performance and performance on the navigation and dissection subtasks for the other models appear to indeed be at steady-state asymptotic levels. (Note that injection subtask scores were at 100 percent for each of these 11 trials, and are consequently not charted here.)

Collapsing across model over these 11 trials for the expert ENT subject, we observe the Pearson product-moment correlation coefficients ("r") shown in Table 5 among these performance variables (critical r = .6021 for $p < .05$, df 9).

Table 5. Correlation matrix showing relationships among subtask and overall performance measures across the final 11 trials by the experienced ENT proctor.

	Trialscore	Navtime	Navscore	Initime	Disstime	Disscore	Trial time
Trialscore	1						
Navtime	.037	1					
Navscore	.856	.119	1				
Initime	-.718	.384	-.608	1			
Disstime	-.643	.29	-.387	.642	1		
Disscore	.557	-.136	.049	-.416	-.593	1	
Trial time	-.609	.424	-.357	.689	.987	-.581	1

These findings suggest that (for this subject, at least) the best asymptotic predictor of overall trial score is navigation score (r = .856), and that the best predictor of overall trial time is dissection time (r = .987), as suggested above.

Non-ENT Proctor Steady-state Performance

When we look at the correlations among these same performance variables for the last six trials of the other highly experience proctor (CA), we see the same result, as shown in Table 6 (critical r = .8114 for $p < .05$, df 4). Again, the best predictor of overall trial score is navigation score (r = .924), and the best predictor of overall trial time is dissection time (r = .657), although the latter relationship is not statistically significant.

Indeed, if we plot the trial times and trial scores for this proctor side-by-side with the values for the expert ENT proctor, we see that they are remarkably similar. In Figures 31 and 32 we see the trial times and scores, respectively, for the non-ENT proctor on the left side of each graph and the expert ENT proctor on the right side of each graph. Again, trial times on the novice model are in the 250-second range, while trial times for the other model condition are in the 550-second range for the non-ENT proctor.

Table 6. Correlation matrix showing relationships among subtask and overall performance measures across the final six trials by the non-ENT proctor.

	Trialscore	Navtime	Navscore	Injtime	Disstime	Disscore	Trial time
Trialscore	1						
Navtime	-.459	1					
Navscore	.924	-.193	1				
Injtime	-.686	.795	-.592	1			
Disstime	-.889	.627	-.664	.657	1		
Disscore	.694	-.805	.37	-.602	-.916	1	
Trial time	-.471	.151	-.27	-.079	.657	-.626	1

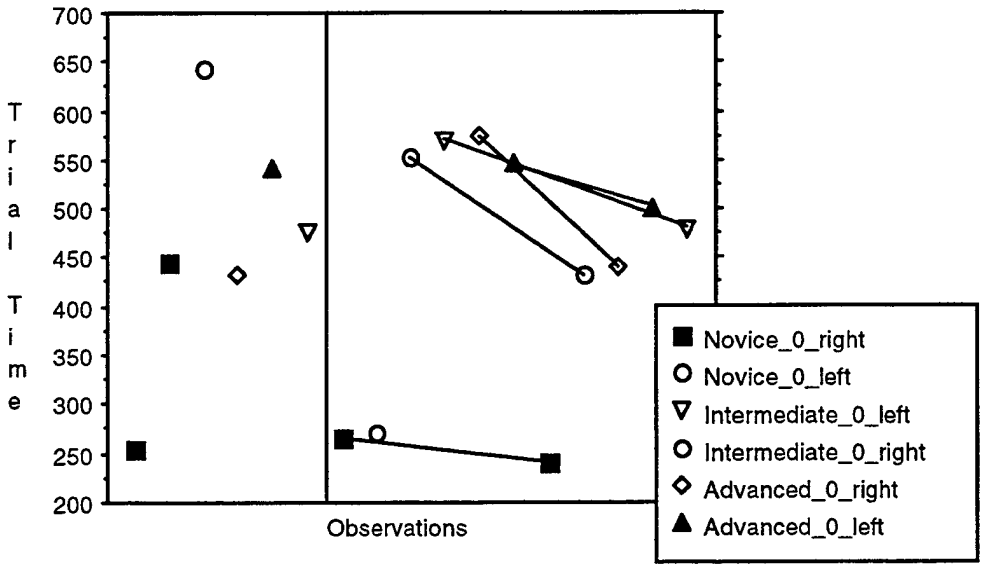


Figure 31. Comparison of asymptotic trial times on each model for the non-ENT proctor and the experienced ENT proctor. Trial times are plotted in order of trial presentation.

These findings suggest that extensive experience with the simulator may afford a non-ENT subject performance values which are comparable with an experienced ENT proctor. Assuming the validation findings discussed above, this bodes well for the training effectiveness of the simulator.

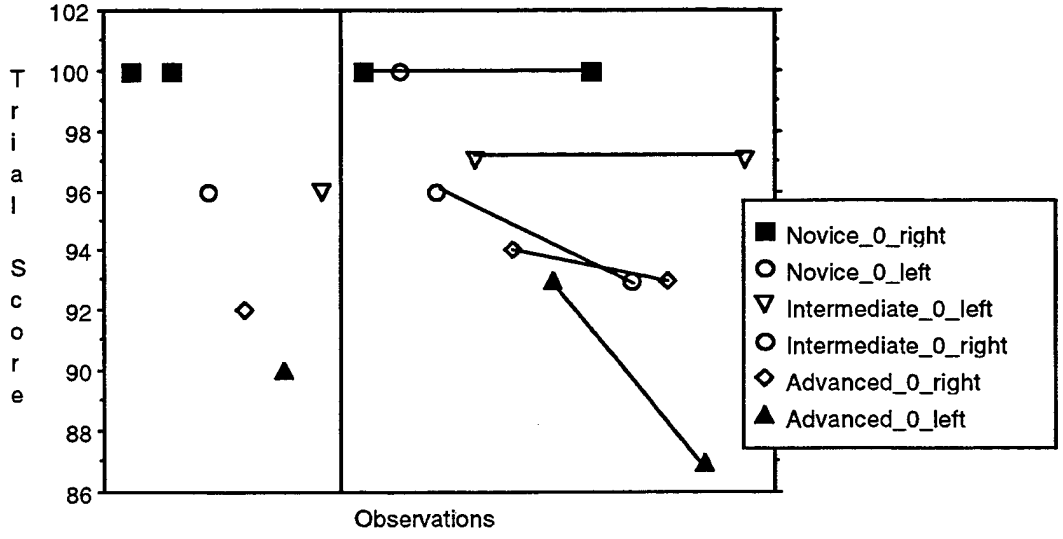


Figure 32. Comparison of asymptotic trial scores on each model for the non-ENT proctor and the experienced ENT proctor. Scores are plotted in order of trial presentation.

3.2.5 Post-Session Questionnaire

All 12 ENT subjects provided us with post-session questionnaire data. All scale responses indicated here are for 10-point scales anchored at the end points.

Proctor's Instructions: Most subjects found the proctor's instructions "very useful" (6/12) or "adequate" (4/12). The one area singled out for improvement was "endoscope and tool handling."

Simulator Layout: Simulator layout and interaction with the model and instruments was rated as moderately realistic (mean = 6.5 and 6.2, respectively).

Abstract Model: The assessed training benefit of the abstract model was relatively variable (mean = 5.3, s.d. = 2.6), perhaps reflecting the variability in baseline experience of the subjects. The assessed training value of each of the five "training aids" (hoops, targets, dissecting spheres, voice feedback, and heart rate) is shown in Figure 33.

As can be seen in these notched box plots (which plot the response percentiles around the median, with the center of the notch being the median and the ends of the box representing the 25th and 75th percentile score), heart rate was viewed as the least beneficial training aid for this model.

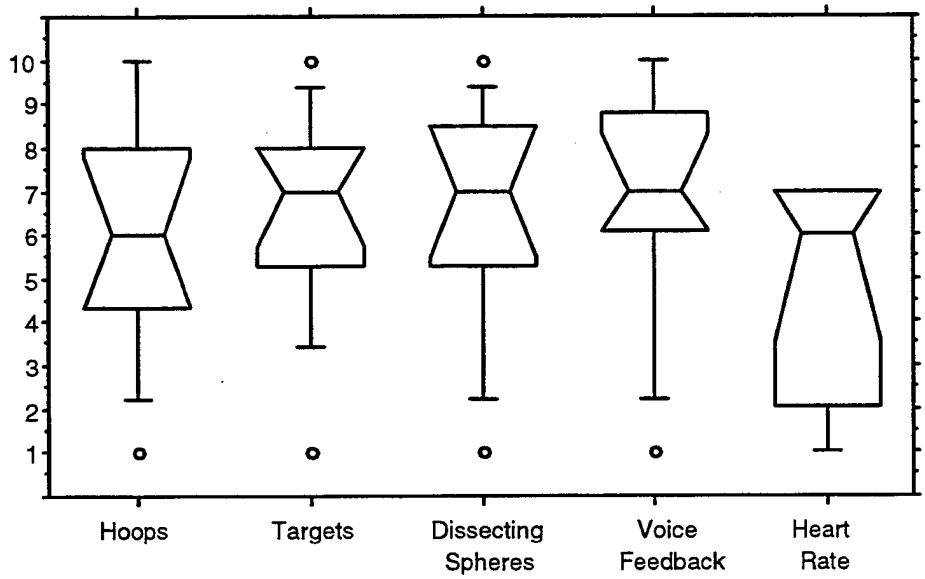


Figure 33. Subject ratings of the training value of each training aid in the abstract ("novice") model (1 = "none," 10 = "significant").

In addition, most subjects indicated that the level of difficulty of the abstract model should remain the same (9 subjects out of 12) or increase (3 out of 12).

Intermediate Model: Subjects overwhelmingly indicated that the experience with the novice model prepared them for Model 2 (mean = 8.3, s.d. = 1.5). Dissection was judged as more difficult in Model 2 than in Model 1 (median = 7.1), while navigation and injection were seen as about the same level of difficulty (median = 5.5 and 5.0, respectively).

Subject ratings of the benefits of the Model 2 training aids are shown in Figure 34. As is evident from the non-overlapping notches in the box plots, the heart rate cue was judged to be significantly less beneficial than the hoops, targets or voice feedback. Furthermore, note that the ratings for these training aids are considerably higher for the intermediate model than for the abstract (novice) model.

One possible explanation for this surprising finding is that in the novice model the cues were useful for training psychomotor skills and instrument control, while in the intermediate model they were *also* useful for training the specific surgical procedure.

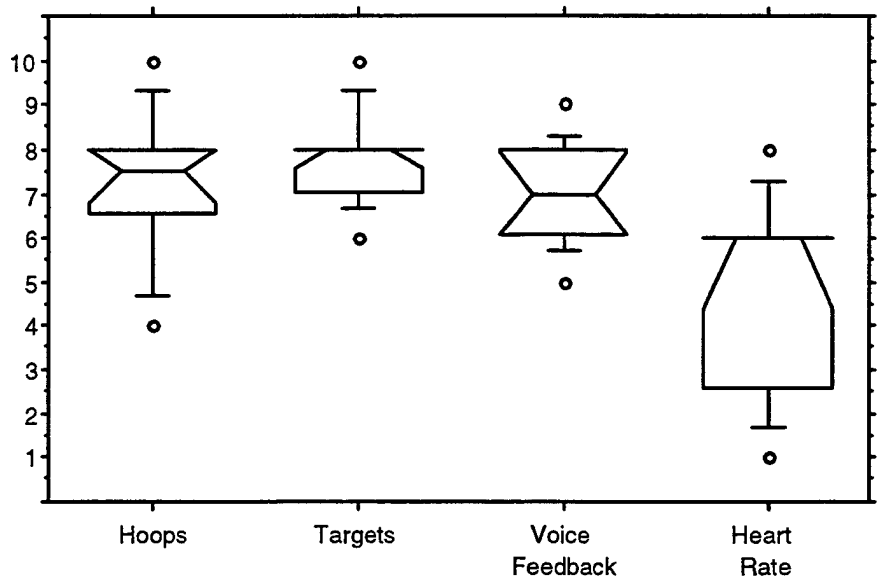


Figure 34. Subject ratings of the training value of each training aid in the intermediate model (1 = "none," 10 = "significant").

Ratings of realism of the anatomical model were also extremely high, with a median across respondents of 8.0 and no ratings below "6" on the 10-point scale. It is also interesting to note (in examining the correlations among survey responses) that the more realistic the anatomical model was rated by these subject, the easier the Model 2 subtasks were perceived to be (r = -.503, -.477, and -.499, for navigation, injection and dissection, respectively).

Advanced Model: Figure 35 presents a summary of the distributions of responses by the ENT subjects to all questionnaire items regarding the advanced model. Responses to question 12 ("model2 benefit") indicate that the vast majority of these subjects felt that the experience with Model 2 was highly beneficial for performing on Model 3.

In rating the difficulty of Model 3 on the three essential subtasks subjects indicated that Model 3 was moderately more difficult than Model 2. Finally, the level of procedural realism for Model 3 was rated quite high, with a median of 8.0 on the 10-point scale ranging from "far from reality" to "close approximation."

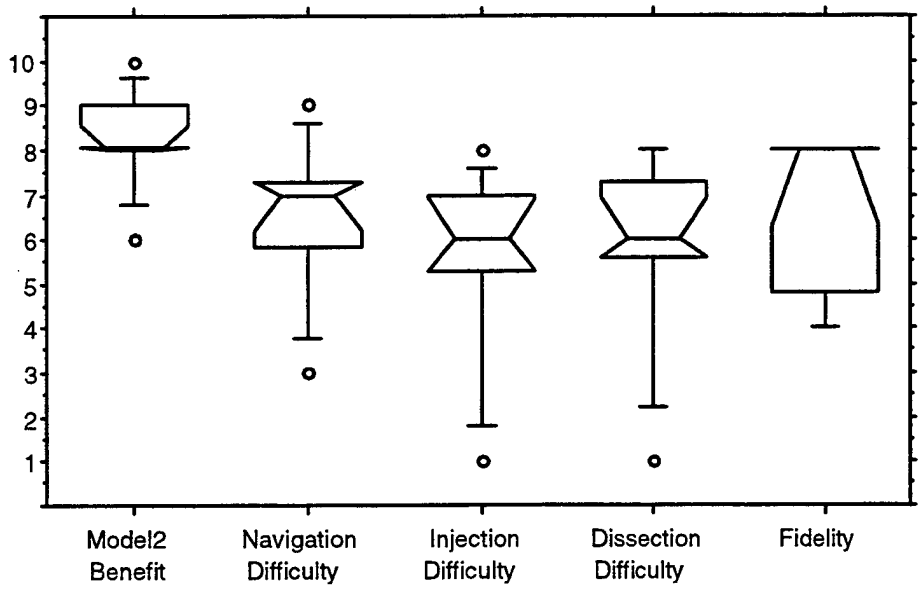


Figure 35. Subject ratings of the training benefit of Model 2 for subsequent performance on Model 3, the difficulty of the three subtasks (1 = "Model 3 easier," 10 = "Model 3 more difficult"), and the fidelity of the simulation in the advanced model (1 = "far from reality," 10 = "close approximation").

Force Feedback: Seven of the 12 ENT subjects rated the use of the haptic subsystem. When asked whether they preferred the force feedback on or off, 4 preferred it "on," one preferred it "off," and one initially preferred it "off" but later preferred it "on." When asked if they preferred the force display on the forceps or on the endoscope, 6 indicated a preference for forces on the forceps, while 1 indicated a preference for forces on the endoscope. (Note that they only experienced the forces on the forceps, not on the endoscope, so these responses were partially speculative.)

Ratings of the realism of the force feedback were moderately low, with a mean of 5.1 and a standard deviation of 1.7 on the 10-point scale from "far from reality" to "close approximation," although one of the 7 subjects rated it an "8" and none of the subjects gave it a realism rating below "3."

Overall Evaluation: Responses to items regarding the overall evaluation of the simulator are summarized in Figures 36 through 38. Level of difficulty of the simulator for the three subtasks is assessed in Figure 36; the results suggest that the tasks were perceived as roughly the same level of difficulty as an actual procedure, with the exception of the dissection task, which is perceived as somewhat more difficult on the simulator.

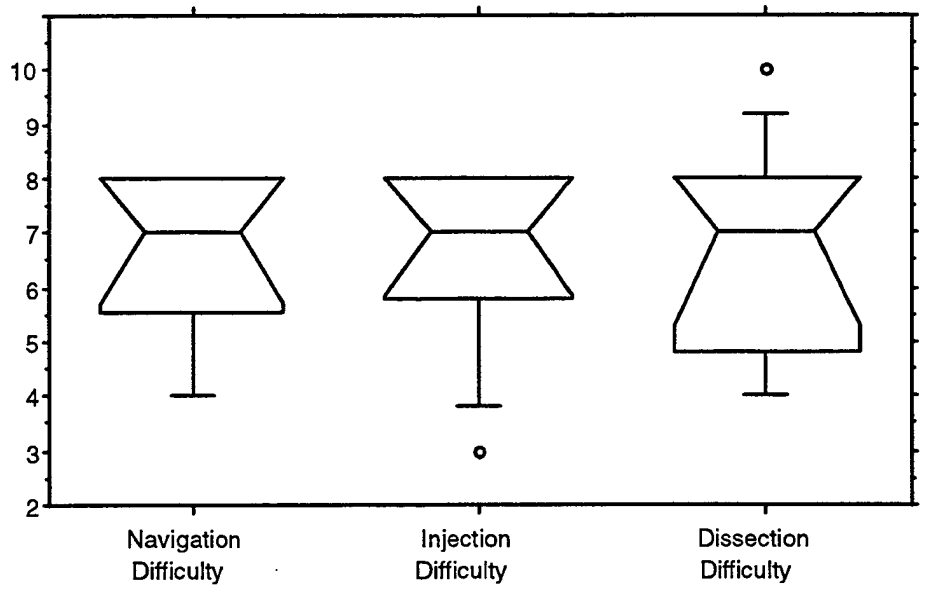


Figure 36. Subject ratings of the overall difficulty of the three subtasks compared with an actual procedure (1 = "simulator easier," 10 = "simulator more difficult").

In assessing the training value of each model for themselves (Figure 37), there appears to be a linear trend from the novice model to the advanced model, with all seen as valuable but the advanced model especially so.

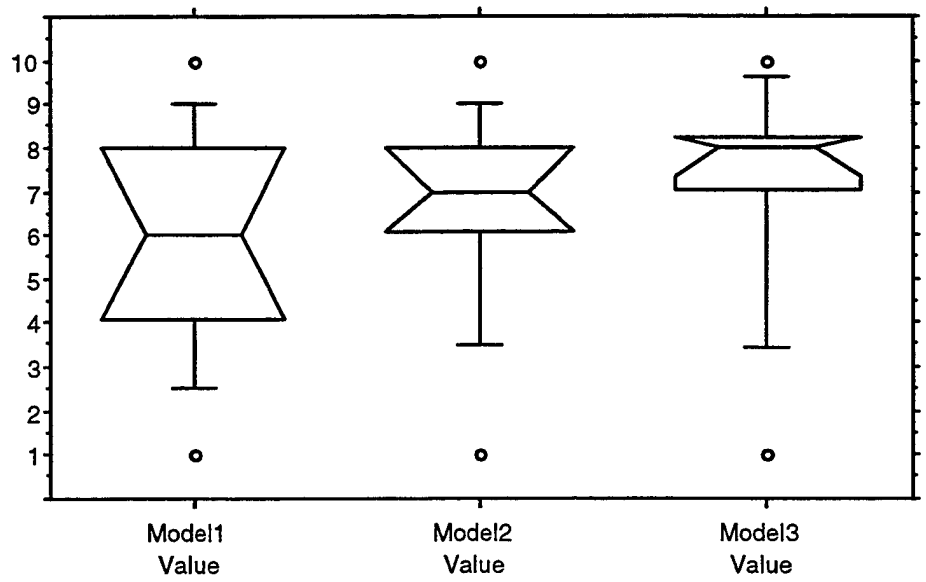


Figure 37. Subject ratings of the overall training value of each of the three models (1 = "none," 10 = "significant").

In assessing the adequacy of the virtual anatomical model for developing proficiency at the common tasks (Figure 38), these subjects indicate that the model is quite adequate for training navigation and injection skills, but may be less than adequate for training dissection skills.

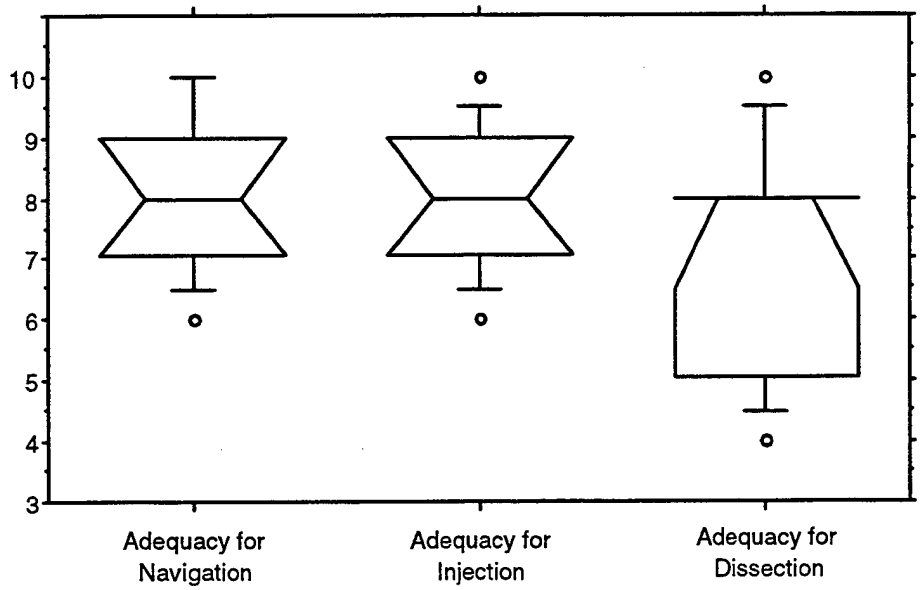


Figure 38. Subject ratings of the adequacy of the anatomical model for developing proficiency at the three common subtasks (1 = "inadequate," 10 = "more than adequate").

When asked to indicate what levels of ENT training would benefit from exposure to the simulator, the 10 ENT respondents offered the following distribution of responses, suggesting that in its current implementation, the simulator is best suited for junior residents (as designed):

med student = 2
R1 = 6
R2 = 6
R3 = 4
R4 = 2
R5 = 2
R6 = 0
All = 4

Finally, would further realism enhance training on the common tasks? All 10 respondents indicated "yes," as we would expect.

3.2.6 Optimal Path Analysis

One promising technique for evaluating user performance on these surgical simulation tasks is to look at the paths of the virtual endoscope and virtual tools over the course of a procedure. A sample of such paths is shown in Figure 39. We have selected a sample of trials to illustrate the variability in user performance.

The colors in the endoscope path renderings (Panels A, B, C, and D) correspond to the three subtasks of the procedure (navigation, injection, and dissection) during a trial on the intermediate model. Note that there are a number of large sweeps outside the main area of activity; these represent the periodic removal of the "bloody" scope to wipe it on the pad on the forehead of the mannequin.

For the tool paths (E, F, G, and H) the colors represent the dissection of each sphere in the novice model. Since the tool for each sphere was automatically chosen by the system in this model (to provide subjects with a systematic exposure to the instrument set), the colors in these paths also represent performance with the various tools.

Tool path scores. In addition to drawing the paths for visual analysis, we calculated a set of objective scores based on the tool path data. The total time taken for each sphere was determined by the number of frames for that segment. These measures effectively translate into overall time, since the frame rate is determined primarily by position of the renderer in the anatomy, which was essentially constant across subjects for each (automatically selected) tool.

A second measure was the mean deviation of the tool position (in each frame) from the centroid of the dissecting sphere for that tool. A third (composite) measure was then calculated for each sphere as:

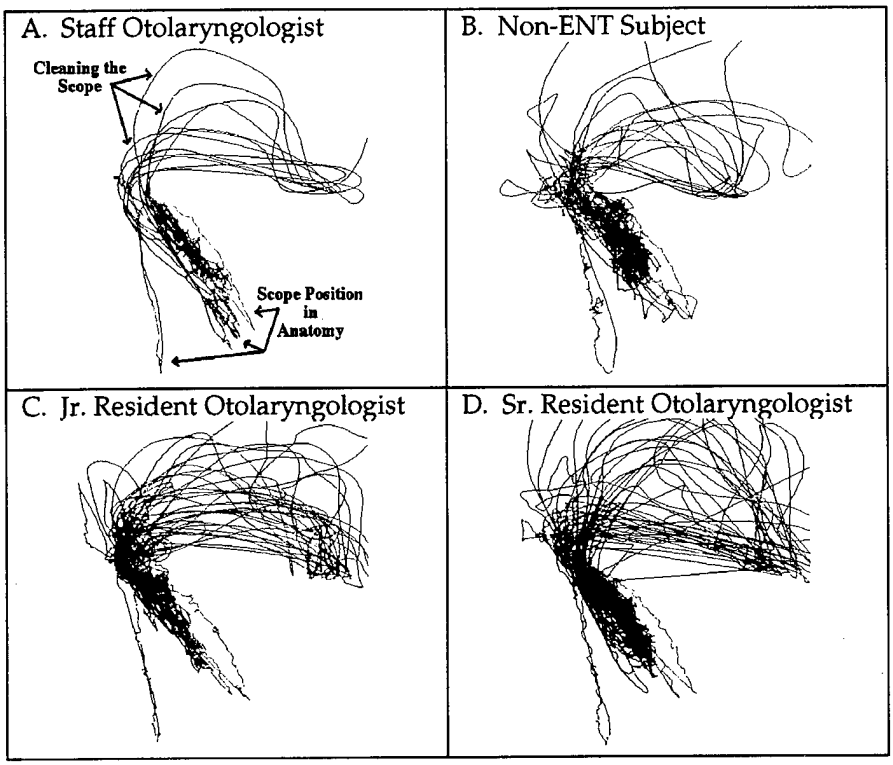
$$\textit{sphere path score} = \textit{total frames} * \textit{mean tool deviation from centroid} / 1000$$

Mean frames/sphere, mean deviation from sphere centroid, and mean sphere path score were also calculated for each subject's path, yielding an overall "path score." Note that for each of these measures (frames, deviation, and path score), the lower the score, the better the performance.

First-order correlations among these new path measures and the other subject performance measures are presented in Table 7 (critical $r = .4060$ for $p < .05$, df 22). As can be seen, the mean frames/sphere and tool path scores were correlated significantly with all other performance measures, and most importantly, dissection score.

In addition, the mean deviation/sphere measure correlated significantly with dissection score, overall score, trial time and navigation score. Note further that all of these significant correlations were in the direction expected. These results may provide validation evidence for the system-generated scoring algorithm.

ENDOSCOPE POSITION DATA:



TOOL POSITION DATA:

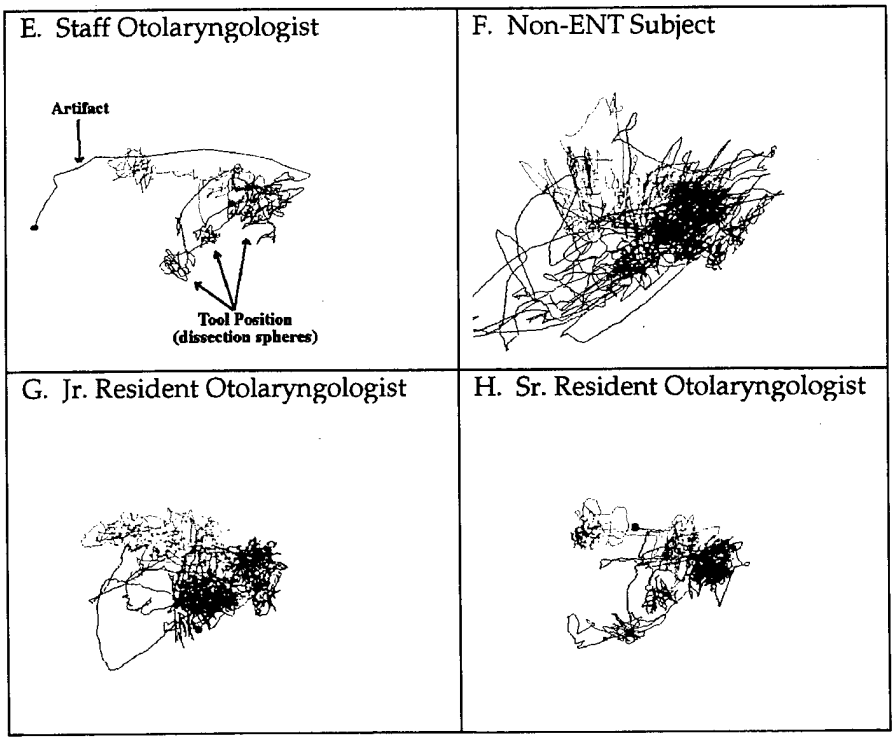


Figure 39. Path renderings for endoscope and tool traversals.

Table 7. Correlation matrix showing relationships between tool path measures and system-generated subtask and overall performance measures for the initial novice trial.

	Path score	Mean dev	Frames/tool
Path score	1		
Mean dev...	.625	1	
Frames/t...	.951	.381	1
Disscore	-.74	-.41	-.76
Disstime	.936	.398	.973
Injscore	-.708	-.269	-.748
Injtime	.814	.364	.837
Navscore	-.559	-.44	-.526
Navtime	.596	.374	.592
Score	-.798	-.439	-.809
Trialtime	.922	.416	.95

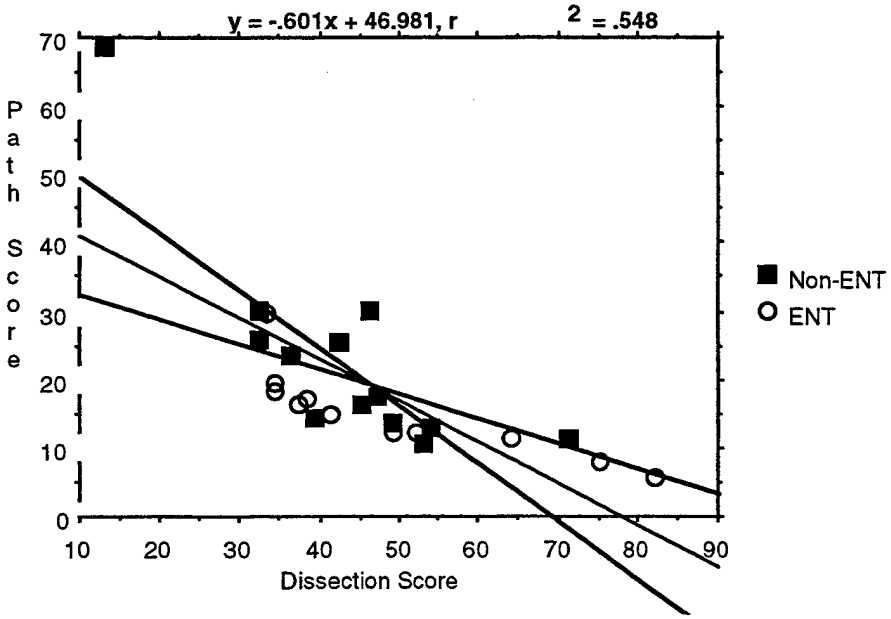


Figure 40. Linear regression for novice tool path score by system-generated dissection score, with 95% confidence limits for the slope of the regression line, broken down by subject group.

The strong (inverse) relationship between the tool path scores and the system-generated dissection scores can be seen clearly in Figure 40. It is interesting to note that the relationship appears to be even stronger for the ENT group alone.

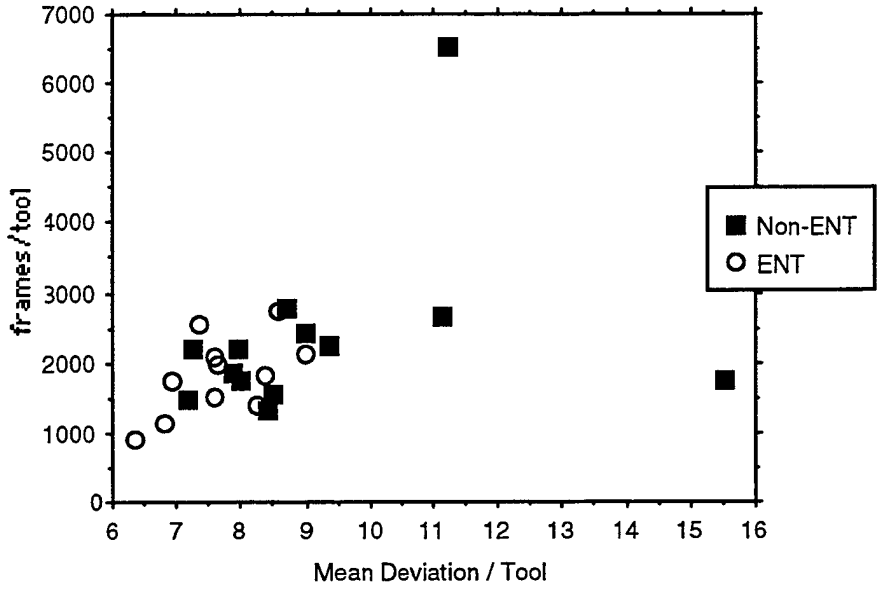


Figure 41. Scatterplot showing the relationship between the two components of the tool path score (mean frames per tool, or sphere, and mean deviation from the sphere centroids) for all subjects on initial novice trial, broken down by subject group.

Figure 41 illustrates the relationship between the two components of the tool path score (essentially, speed and accuracy). Points closest to the origin on both axes reflect better performance. It can be seen that the ENT scores cluster much closer to the origin.

In examining these differences further using students' t, we find that the non-ENT subjects did indeed deviate significantly more from the sphere centroids (ENT mean = 7.66, s.d. = .807, non-ENT mean = 9.22, s.d. = 2.27, p = .0422). However, their time scores (ENT mean = 1883 frames/sphere, s.d. = 562.25, non-ENT mean = 2381 frames/sphere, s.d. = 1327.07, p = .2162) and overall tool path scores (ENT mean = 15.06, s.d. = 6.49, non-ENT mean = 23.24, s.d. = 15.33, p = .1142), while worse, were not significantly so.

3.2.7 Proctor Observations

A number of significant insights can be gleaned from subject's open-ended comments, informal observations by the proctor, and problems experienced during trials. Following are some observations and recommendations derived from the proctors' experiences.

Haptics

Subjects (most notably the residents and ENT staff) had difficulty with the need to steady their thumb to control the instrumented forceps during injection and dissection. This stabilization while opening and closing the forceps was required to keep the tip of the virtual tool from moving away from the area of interaction. This need for stabilization has been attributed to a lack of realistic haptic feedback.

While the version of the haptics subsystem tested here was somewhat rough, Version 1.3 of the software (not yet formally evaluated) has made significant improvements to the haptics, also

providing a much more realistic representation of grasping, tearing and injecting the virtual tissue. Grasping of the virtual tissue is represented by a "hold" on the tip of the instrumented forceps, after closing the jaw on the tissue, as if holding onto a static object. Tearing of virtual tissue is represented by a resistive force on the tip of the instrumented forceps as it is being pulled away from the "hold" position, with a final "release" after a predetermined distance. Injecting is represented by a "pop" when initially passing the virtual needle through the tissue and a "hold," keeping the instrumented forceps static in the X,Y,Z position, but not the heading, pitch and roll.

In addition to these enhancements for stabilization, the suction tool is "pulled" toward the virtual tissue based on its proximity, an initial "jolt" is placed on all tools when initially interacting with the virtual tissue and the feel of the sickle knife simulates cutting paper with a straight razor. These improvements have added a tremendous amount of realism, not only to the injection and dissection tasks, but also to the realism of navigating the instrumented forceps through the sinus cavity. These improvements will be implemented and tested in the next phase of the simulator's development.

Retraction of Instrumented Forceps

During pilot studies, when subjects wanted to swap tools, they were required to retract the instrumented forceps from the sinus cavity (retracting to just posterior to the columella nasi) before acquiring the new virtual instrument. This requirement was the major contributor to two problems with the encoders on the instrumented forceps. The first problem took place during the pilot studies; the retraction of the instrumented forceps caused the endoscope shaft to collide with the encoders measuring the heading and pitch of the instrumented forceps, which then caused either fraying or displacement of the cables on the sectors of the encoders.

The second problem was interaction of the sectors of the encoders and the hard palate of the mannequin during retraction. This interaction forced rotation of the sectors, introducing an offset in the initial calibration of the instrumented forceps and therefore an offset in the vector of the virtual tool. The problem was resolved by applying LocTite to the sectors and eliminating the requirement that the subjects retract the forceps during instrument swapping. Immersion Corporation is currently upgrading and improving the design of the instrumented forceps encoders for the next phase of the evaluation.

Hummer Speed

The typical microdebrider in the OR operates at 3000 RPM. Experienced surgeons develop a certain rhythm to dissection, and expect and anticipate a certain volume of tissue to be removed over time. In version 1.2 of the simulator, the dissection speed is at best "quarter speed." More experienced surgeons perhaps became impatient with this rate of dissection, and may have had a tendency to move on to another area of the anatomy to dissect, to the detriment of their dissection scores. It also appeared frustrating to have areas in version 1.2 that should have been dissectable but would not dissect.

Ambiguity in the Posterior Ethmoid

In the posterior ethmoid, the model takes on an amorphous look, making it somewhat difficult to determine what to dissect next. The inexperienced sinus surgeon would simply dissect anything that would disappear. For the experienced surgeon, who knows that you cannot dissect with reckless abandon for fear of creating a major complication, dissection naturally slows down in this area close to the carotid artery, optic nerve and skullbase. In addition, the surgeon normally relies heavily on

haptic cues on dissecting posterior ethmoid cells. The absence of haptic cues in an amorphous environment creates an anxious situation for the experienced sinus surgeon. The improved haptic system in version 1.3 is likely have significant impact on dissection performance in this region.

Grabbing Bone Fragments with Jawed Tools

Removal of two bone fragments from the uncinate process and three bone fragments from the bulla ethmoidalis, which were required for a complete score, was unrealistic, due to the difficulty in grasping with the jaw of the virtual tool; the fragments could only be grasped at their center. Regardless of skill, subjects were required to learn how to grasp the bone fragments in the simulator and required instruction by the proctor on how to do so. Many of the staff and resident ENT surgeons initially tried to grasp the bone fragments on their edge, as they would in a real surgical environment, but without success. Version 1.3 has corrected this problem by allowing a jawed virtual tool to grasp the bone fragments anywhere along its circumference as well as at its center.

Improvement of the Virtual Suction Tool

During testing, the suction tool's only function was to reduce the volume of the blood spheres inside the anatomy after dissection of part of the tissue. It was brought to our attention that in a surgical environment the ENT surgeon would use the real suction tool not only to remove blood, but also to remove small amounts of tissue and mucous in the posterior ethmoid cells, and bone fragments throughout. Version 1.3 allows a small amount of dissection by the virtual suction tool, as well as the ability to grasp and slowly remove bone fragments.

Need to Break Up Model 1 into Separate Tasks for Non-Physician Group

During pilot testing of the non-physician group, it was discovered that an initial verbal summary of the task to be performed, without a visual example of the task, was overwhelming to the untrained/ unfamiliar subject. The need for the subject to memorize each subtask and also to gain an understanding of what was needed to complete the task proved to be too demanding. The original presentation of the material consisted of a videotaped introduction to the simulator (described below) followed by verbal instructions by the proctor, describing each subtask (navigation, injection and dissection) in order and in totality.

The subject was next introduced to the endoscope and instrumented forceps and instructed in their functions for each task. Then the subject was asked if there was anything which needed further explanation. We found that the proctoring instructions needed to be repeated multiple times throughout the trial to reinforce what the task entailed. By trial and error, it was finally decided to split each subtask into three independent tasks for their initial trial on the simulator. This breakdown was required only for their initial trial.

Ability to "Push Through" the Virtual Anatomy During Trials

While performing the three tasks, subjects had the ability to push through the virtual anatomy with the shaft of both the virtual endoscope and the virtual tool. The staff ENTs expressed greatest concern with the virtual *tool* passing through the virtual anatomical structures during injection and dissection. A potential, but expensive and cumbersome, solution to this problem would be implementation of haptics with 6 degrees of freedom on the instrumented tool. This solution would be too cumbersome to implement in the current design of the mannequin box, but should be considered for future designs.

The unrealistic ability of the virtual *endoscope* to pass through the anatomy, however, was welcomed by the majority of the staff ENTs. When the virtual scope passes through the anatomy, the image on the monitor disappears and the screen turns black until the position of the instrumented endoscope is maneuvered back inside the anatomical model. This solution was seen as helpful because the residents were taught to concentrate on staying within the anatomy for the duration of the procedure without potentially traumatizing real tissue in the operating room. This was seen as one of the many advantages of using the simulator to gain the hand-eye coordination necessary to maneuver the endoscope through the anatomy.

Ability to see Maxillary Ostium for Antrostomy

Although the subjects were told to perform a limited ethmoidectomy, the antrostomy of the maxillary ostium was removed from the requirements during the procedure on the simulator because of the inability to realistically view the ostium. After dissection of the uncinate process in an actual procedure, the maxillary ostium would be in view with a zero or 30° scope and the antrostomy would easily be conducted. After dissecting the uncinate process in the simulation, however, to view the ostium required a 70° scope, with unrealistic positioning of the scope inside the sinus cavity. To correct this problem, Version 1.3 allows dissection of the uncinate process more superior/laterally and inferior/laterally than Version 1.2. This added realism will be tested and evaluated in the next phase of the evaluation of the simulator.

Instructional Video

An instructional video was made to introduce the subjects to the simulator to aid in standardizing instructions across subjects. The video was designed to instruct students on the procedure, the anatomical structures inside the sinus cavity, and all available tools at their disposal.

The content structure of the original videotape is:

Endoscope and Forceps

- Introduction to the instrumented endoscope
  - How to handle it
  - The need and process for stabilization using both hands
  - Hints on guiding the scope, by use of angles, through the anatomy
  - How to eliminate the effects of your natural tremor
  - Introduction to transferring the tool across the columella nasi
  - Instructions on cleaning the scope when it becomes "bloody"
  - Hints on alignment of the scope within the plane of the mannequin to keep track of your heading and orientation
  - The scope's ability to rotate the image, by axially rotating the shaft of the scope
  - Explanation of 30° and 70° scopes and their uses to view around corners
- Introduction to the instrumented forceps
  - Limitations of the subject's ability to fully retract the forceps
  - Rationale for passing the forceps across the columella nasi
    - Their rigid connection to the mechanics of the haptics inside the mannequin
  - How to swap tools in Models 2 and 3
    - Calling out the desired virtual instrument

- Retracting the forceps to just posterior to the columella nasi to receive the desired virtual instrument

Body Positioning

- Keeping your body parallel with the mannequin
  - Turning head to see the monitor instead of turning body

Anatomy

- Introduction to major anatomical structures on physical "pull away" model
  - Nasal passage, septum and nasopharynx
- Introduction to sinus cavity anatomical structures on physical "pull away" model
  - Superior, middle and inferior turbinates, uncinate process and bulla ethmoidalis
- Description of anatomical structures which will be interacted with and removed during procedure
  - Definition and procedure for a limited ethmoidectomy
- Description and demonstration of sites for injection during procedure in models 2 and 3
  - Medial middle turbinate, root of uncinate process and the lateral nasal wall
- Description and "pull away" of dissection tasks for models 2 and 3
  - Medialization of middle turbinate and dissection of uncinate process, bulla ethmoidalis and widening of the maxillary ostium

Procedures

- Playback of video of novice model, performed by Dr. Edmond, no voice-over to allow the proctor to discuss the trial with the subject
- Examples of all virtual instruments available to the subject
- Playback of video of intermediate model, performed by Dr. Edmond, no voice-over to allow the proctor to discuss the trial with the subject
- Playback of video of Model 3, performed by Dr. Edmond, no voice-over to allow the proctor to discuss the trial with the subject

The video proved to be too advanced for the non-physician group, presenting an excessive amount of information for the untrained or unfamiliar subject. Pilot subjects from this group who were shown the video reported being confused as to what was required of them. Specifically, these subjects did not have enough time to comprehend both the simulator interface and the purpose of the procedure being simulated.

Future work is planned in this area to create group-specific videos for each subject group. Shortening the duration of the instructional video will make the testing protocol more efficient, and automating more of the proctoring instructions will permit a single proctor to complete all necessary tasks without difficulty.

4 CONCLUSIONS AND RECOMMENDATIONS

4.1 Procedural Validity

The validity of the simulator for the ESS domain is suggested by a number of findings:

- ENT subjects performed better than non-physician subjects on both the novice (abstract) and intermediate (anatomical with aids) models
- Initial performance on the novice model was correlated with residency level and degree of prior ESS experience
- Patterns of difficulty for asymptotic performance on the simulator seem to match the typical pattern of subtask difficulty in the OR
- Subject ratings of the realism of the virtual anatomical model were consistently high on the post-session questionnaire and in open-ended comments
- Post-training questionnaire responses confirm that the simulator was generally perceived as valid and useful for ESS training by the ENT subjects

4.2 Curriculum Design

The ESS simulator takes medical simulation several major steps forward in its evolution. Aside from its technical accomplishments, the integration of a well thought-out curricular framework allows it to take advantage of virtual reality without sacrificing the benefits of more traditional computer-aided instruction.

Model 1 introduces the student into an abstract environment, allowing the student to gain the required hand-eye coordination with the endoscope and the special skills needed to maneuver the instrumented forceps, without requiring them to concentrate on anatomy.

Model 2 introduces the student to the anatomy, but still utilizes the training aids from Model 1. This model gives the student the help of hoops for the initial passes through the anatomy, targets for injection areas and labels on the anatomical structures with which interaction is necessary. The educational advantages of simulation can best be achieved with a model of this kind.

Model 3 introduces the student to a more realistic environment. There are no longer any training aids to guide the student through the procedure. For navigation of the scope, the student must rely on what was learned when navigating through the hoops in Model 2. For injection, the student must remember where injection of the vasoconstrictor is useful. For dissection, the student has no labels to indicate what anatomy to interact with, and so must rely on what was learned in Model 2 to perform the procedure.

4.3 Future Directions for Evaluation

4.3.1 Scoring Algorithm Validation

Considerable attention was given to the scoring algorithm currently implemented in the system, in an attempt to capture the primary clinical performance factors. Still, it is somewhat complex and ad hoc, and deserves more detailed analysis and validation.

In the next evaluation phase we will attempt to correlate the algorithmic scores with independent measures of surgical skill, and adjust the optimal values appropriately. A further refinement will be to normalize the algorithm across models to facilitate comparisons and arrive at a common criterion for advancement.

4.3.2 Optimal Instrument/Scope Path Analysis

The optimal path techniques introduced above are compelling because of their "face validity" but will require further development.

Tool path analysis. Preliminary pilot data indicate that these tool path efficiency measures closely reflect observers' subjective rankings of path "goodness." The validity of these measures will be studied more formally in the next evaluation phase. In addition to calculating overall scope and tool path scores, we will look more closely at user performance with the individual tools in the virtual instrument set and at the effects of anatomical position on performance with each tool.

Determination of the clinically acceptable range of path scores is desirable for several reasons, including the development of training protocols that reinforce appropriate skills. The range of path scores is bounded on the low end by the radius of the dissecting spheres and the minimal time to dissect (which is not known, but can be approximated by the asymptotic performance of an experienced ENT surgeon.

The constraints on the high end are not as clear (at least for the time component), and should perhaps be determined clinically. While theoretically a surgeon could take infinitely long to perform a procedure, there are several practical and clinical constraints, including the increased risk to the patient during protracted procedures.

Scope path analysis. We have not yet attempted a quantitative analysis of the endoscope path data. In the next evaluation phase we will experiment with various methods of determining mean deviation from the optimal scope path. Initially the most direct path between the training aids (hoops, targets and dissecting spheres) may serve as an optimal path, but this approach does not take into account the surgeon's knowledge and skill in navigating around critical anatomical structures.

A more appropriate approach might be to calculate the optimal path using a robust lowess regression technique on the datasets from a group of experienced ENT surgeons, and then determine the mean deviation from that optimal path for each subject.

4.3.3 Evaluation of Improved Haptics

The value of the haptic feedback subsystem to the simulator was assessed only subjectively in the current phase. In general, it was perceived to be only moderately useful, and we suspect that the relatively poor performance on the dissection task, in particular, may have been due largely to inadequate feedback about the tissue forces.

As described above, preliminary evaluation of Version 1.3 suggests that the haptic subsystem is greatly improved. The improved system will allow us to evaluate more formally its impact on training trial performance and its contribution to OR performance. In addition, we will investigate more formally the relative merits of force feedback on the endoscope versus the instrument.

4.3.4 Transfer of Training

Transfer of training to the real operative environment is the primary objective of this procedural simulator, and will be the primary focus of the next phase of our research. In preparation for that phase, we have collected initial OR videotape data from several first-time ESS procedures by residents for whom we have previous simulator performance data. These tapes will be formally analyzed for subtask proficiency, as rated by their attending staff instructors, to derive a set of systematic measures of performance on the target task. These will then be correlated with prior simulator experience for current and entering residents to determine the training effectiveness of the simulator and to provide guidance for its further development.

4.4 Model Enhancements

As noted earlier, the development team elected to focus the first iteration of the ESS simulator (appropriately) on the needs of junior residents. Several enhancements to the library of available anatomical models are currently being integrated which are intended to extend the utility of the system to senior residents and more experienced staff physicians.

Appropriate enhancement implementation will require iterative formative evaluation, as before, and the training utility of each enhancement will need to be assessed. Transfer of training may need to be assessed indirectly in some cases, since real-world incidence of certain conditions of interest may be infrequent under normal conditions.

4.5 Criterion Performance Standards

One longer-term objective of this evaluation activity will be to determine the clinically acceptable range of user performance scores on the simulator, including those generated by the basic scoring algorithm and those calculated from the optimal path data. Further, more detailed analysis of these scores (e.g., time vs accuracy for specific tools) will also provide us with useful information for customizing training protocols for individual residents.

Ideally, subject performance on the simulator will be reliably predictive of OR performance. Achievement of this correspondence will enable us to better establish performance criteria for advancement through the protocol. In a sense, the scoring algorithm represents a theoretical model of surgical proficiency; additional validation studies of the simulator will help to correct and refine those theoretical models.

In addition to the learning curve for simulator performance over time, the distribution of trials over time is also of interest. For our "steady-state" proctors, for example, the temporal distribution of training trials was highly variable, ranging from several trials per day to one trial every 2-3 weeks. Routinely collecting repeated measurements on resident subjects will enable us to explore the optimal number and timing of training trials in the residents' curriculum. Undoubtedly some degree of trial spacing (as opposed to massed practice) will prove most effective, as has been shown in many other domains; of interest is just what that spacing strategy should be for ESS procedure training.

Ultimately, we may also be able to establish an equivalence between time on the simulator and time in the OR. Such a correspondence would be useful for residency curriculum development, and perhaps eventually for professional credentialling. Such a system would be of significant benefit for patients, and could greatly extend accessibility to procedural training opportunities.

5 SUMMARY

This study presents the results of our systematic evaluation of a high-end virtual reality simulator aimed at training a set of skills essential to endoscopic sinus surgery. Our findings suggest that the simulator represents a valid and useful implementation of the target ESS tasks. In addition, the thoughtful integration of an organized curriculum perspective makes this system uniquely valuable among emerging medical simulation systems.

This study also suggests a framework for incorporating systematic evaluation into the process of developing procedural training simulators in the medical domain. Incorporating both formative and summative aspects of evaluation has greatly enhanced the development process and assures the continuing evolution of a usable and effective system.

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APPENDIX F

SURGICAL NEEDS SURVEY

DEPARTMENT OF THE ARMY
HEADQUARTERS, MADIGAN army MEDICAL CENTER
TACOMA, WASHINGTON 98431-5000

REPLY TO
ATTENTION OF

18 October 1995

As you recall, Madigan AMC has been funded to develop a prototype surgical simulator for endoscopic paranasal sinus surgery. The focus of the project is to explore ways of using advanced technology in the form of a surgical simulator, to assist providers with acquiring the skills necessary to perform safe and effective endoscopic sinus surgery. We are exploring the full range of training, from novice to expert.

We are asking a select group of physician for input to help quide the clinical team involved with the development of the simulator. Your input will be used to help focus our efforts.

As you know, the technology is advancing rapidly. Our goal is to develop a visually realistic, highly interactive, patient specific surgical simulator for training. However, a single solution is not the answer. For example, what is important for the novice is not necessarily important for the expert. You can assist us by defining what is important at each level. We will analyze this information and use it to develop the first iteration of the simulator. It is our belief that in the future this technology will contribute significantly to the develop of future Otolaryngologist.

Sly, if you could distribute this questionnaire to Dr's Hayes, Liening, Teller and Malis, I would appreciate it. Please have them return it as soon as possible. If you could batch them and send it back that would work best.

Sincerely,

Charles V. Edmond Jr. ~~MAJ~~. MC.
Director of Residency Research
Madigan Army Medical Center

At each level of training, the needs of the surgeon differs. Please score from 1 (critical need) to 7 (not important) for each level of training.

	NOVICE Med Student-PGY3	**INTERMEDIATE** PGY3-PGY4	**EXPERT** PGY4-BEYOND
Visual Realism			
Spatial Awareness (anatomic 3-D orientation			
Haptic Interaction (touch-feedback)			
Patient Specific model			
Psychomotor Development			
Interactivity (response of application to user)			
Computer-aided dissection (real-time localization during surgery)			
Demonstration of standard surgical procedures			
Demonstration of complications			
Advanced surgical techniques			
Sinus pathophys. / medical management			

Please rank order from 1-11 for each level of training (novice-expert).

	NOVICE Med Student-PGY3	**INTERMEDIATE** PGY3-PGY4	**EXPERT** PGY4-BEYOND
Visual Realism			
Spatial Awareness (anatomic 3-D orientation			
Haptic Interaction (touch-feedback)			
Patient Specific model			
Psychomotor Development (hand-eye coordination)			
Interactivity (response of application to user)			
Computer-aided dissection (real-time localization during surgery)			
Demonstration of standard surgical procedures			
Demonstration of complications			
Advanced surgical techniques			

Sinus pathophys. / medical management			

In paragraph form, please describe your thoughts as they pertain to surgically simulated endoscopic paranasal sinus surgery.

1. What is the importance of visual realism, when trying to graphically represent anatomy and surgical procedures at all levels of training?

2. How important is anatomic spatial awareness at all levels of training?

3. While simulating the operative procedure, how important is forced feedback? (computer generated forces that mimic the forces encountered in an actual procedure).

4. How important is a patient specific model?

5. How important would it be to demonstrate paranasal sinus pathophysiology, medical management, advanced applications, surgical complications in a simulated environment or as computer aided instruction?

6. Is there any benefit in using the simulator to assist the user with the development of his/her psychomotor skills? (ie. handling the rigid scope while dissecting).

7. What areas should we address that are not included on this questionnaire?

APPENDIX G

TRIAL MATRIX FORM

TRIAL OPERATIONS

	Name:	Subject # :								
	Trial Type:									
		Navigation			Injection			Dissection		
		Beg.	Mid.	End	Beg.	Mid.	End	Beg.	Mid.	End
Training Aids										
X	Labels									
	Targets									
	Hazards									
	Markers									
	Hoops set #1									
	Hoops set #2a									
	Hoops set #2b									
	Hoops set #3									
Scopes										
	0°									
	30°									
	70°									
CT View										
	Endoscope									
	Tool									
X	None									
Complications										
	Heart Distress									
Patient Options										
X	Bleeders									
X	Bone Fragment									
Audio										
X	Cues									
X	Heart Monitor									
Tool Options										
X	Blood E. Scope									
	Ret. Req. Chge									
Surgical Instruments										
	Freer									
	Needle									
	Bent Needle									
	Sickle Knife									
	Microdebrider									
	Suction									
	Straight-biting Forceps									
	Up-biting Forceps									
	Left-biting Forceps									
	Right-biting Forceps									
X	NULL									

NOTES:

APPENDIX H

PRE-SESSION SURVEY

ENDOSCOPIC SINUS SURGERY SIMULATOR
Pre-training Questionnaire

S#_____ Date _____

Location _____ Proctor _____

==========

M___ F___ Age ____ Left-Handed ____ Right-handed ____

Occupation: MD_____ Specialty: _____

Type of Practice (Academic/research/community-based, etc):

_____

Other: _____

Any factors that might affect your performance today (lack of sleep, medication, etc):

_____

Videogame experience: ___none ___ once ___ occasional ___ often

Virtual Reality experience: ___none ___ once ___ occasional ___ often

Simulator experience: ___none ___ once ___ occasional ___ often

Specify: _____

==========

If non-oto **surgical** specialty:

Years of surgical **training**: _____ # Years of surgical **practice**: _____

Endoscopic procedures **performed**: __0 __1-5 __6-20 __20-100 __>100

Endoscopic procedures **observed**: __0 __1-5 __6-20 __20-100 __>100

==========

If **otolaryngologist**:

Years of oto specialty **training** : ____ # Years of oto specialty **practice** : ____

ESS procedures (sides) **performed**: __0 __1-5 __6-20 __20-100 __>100

ESS procedures (sides) **observed**: __0 __1-5 __6-20 __20-100 __>100

ESS **teaching** experience (students): __0 __1-5 __6-20 __20-100 __>100

How did you learn endoscopic surgery (courses, cadaver dissection, etc)?

_____

APPENDIX I

POST-SESSION SURVEY

ENDOSCOPIC SINUS SURGERY SIMULATOR
ENT Post-training Questionnaire

S#_____ Date_____

Location_____ Proctor_____

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Simulator Preparation

1. How did you find the videotape and the proctors instructions?

insufficient adequate very useful

2. If you answered "insufficient", what areas of instruction do you feel could benefit from more detailed emphasis?

introduction endoscope and tool handling body positioning

anatomy abstract model model with aids

model without aids OTHER_____

OTHER COMMENTS_____

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Simulator Layout

3. From your operative sinus experience, how closely does the simulator layout resemble your operative set-up?

Not at all Identical
1 2 3 4 5 6 7 8 9 10

4. How closely does your interaction with the physical model (mannequin) endoscope and forceps resemble an actual sinus procedure?

Not at all Indistinguishable
1 2 3 4 5 6 7 8 9 10

OTHER COMMENTS_____

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Abstract (Novice) model - The intent of the abstract model is to provide a simple environment for the user to focus completely on skills enhancement (navigation, injection & dissection). The following questions will focus on the training benefit of the abstract model.

5. At your present endoscopic skill level, what training benefit did the abstract model provide you?

None Significant
1 2 3 4 5 6 7 8 9 10

6. What training value did you find in the following training aids?

	None									Significant
hoops	1	2	3	4	5	6	7	8	9	10
targets	1	2	3	4	5	6	7	8	9	10
dissecting spheres	1	2	3	4	5	6	7	8	9	10
voice feedback	1	2	3	4	5	6	7	8	9	10
heart rate	1	2	3	4	5	6	7	8	9	10

7. Should the level of difficulty be changed in the abstract model?

increased no change decreased

OTHER COMMENTS_____

_____

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Sinus model <u>with</u> training aids present (Model 2)

8. Did your experience in the Novice Model prepare you for Model 2?

Not at all Significantly
1 2 3 4 5 6 7 8 9 10

9. In comparison to the Novice Model, did you find the tasks easier or more difficult in Model 2?

	Model 2 Easier				Same					Model 2 More Difficult
navigation	1	2	3	4	5	6	7	8	9	10
injection	1	2	3	4	5	6	7	8	9	10
dissection	1	2	3	4	5	6	7	8	9	10

10. Were the training aids of benefit in Model 2?

	None									Significant
hoops	1	2	3	4	5	6	7	8	9	10
targets	1	2	3	4	5	6	7	8	9	10
voice feedback	1	2	3	4	5	6	7	8	9	10
heart rate	1	2	3	4	5	6	7	8	9	10

11. Did the virtual sinus anatomy geometrically and anatomically approximate a representative endoscopic sinus surgery?

Far from reality — Close approximation
1 2 3 4 5 6 7 8 9 10

OTHER COMMENTS_____

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Sinus model <u>without</u> training aids present (Model 3)

12. Did your experience in Model 2 prepare you for Model 3?

Not at all — Significantly
1 2 3 4 5 6 7 8 9 10

13. In comparison to the Model 2, did you find the tasks easier or more difficult in Model 3?

	Model 3 Easier				Same					Model 3 More Difficult
navigation	1	2	3	4	5	6	7	8	9	10
injection	1	2	3	4	5	6	7	8	9	10
dissection	1	2	3	4	5	6	7	8	9	10

14. In Model 3, how closely does the simulation replicate an actual sinus procedure?

Far from reality — Close approximation
1 2 3 4 5 6 7 8 9 10

OTHER COMMENTS_____

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Force Feedback

15. Did you prefer the force feedback on the forceps? On Off

16. If you had a choice between having forces on the forceps or endoscope, which would you prefer? Forceps Endoscope

17. How closely did the force feedback mimic an actual procedure?

Far from reality — Close approximation
1 2 3 4 5 6 7 8 9 10

OTHER COMMENTS_____

Overall Evaluation

18. How does the level of difficulty in the simulator compare with an actual procedure for the three tasks?

	Simulator Easier				Same					Simulator More Difficult
navigation	1	2	3	4	5	6	7	8	9	10
injection	1	2	3	4	5	6	7	8	9	10
dissection	1	2	3	4	5	6	7	8	9	10

19. At your present level of experience, what training value (for yourself) did you find in each of the models?

	None									Significant
Model 1	1	2	3	4	5	6	7	8	9	10
Model 2	1	2	3	4	5	6	7	8	9	10
Model 3	1	2	3	4	5	6	7	8	9	10

20. Is the present level of anatomic representation in Model 2 and 3 adequate for developing proficiency at the common tasks?

	Inadequate									More than adequate
navigation	1	2	3	4	5	6	7	8	9	10
injection	1	2	3	4	5	6	7	8	9	10
dissection	1	2	3	4	5	6	7	8	9	10

21. What levels of ENT training would benefit from exposure to the simulator? (circle as many as indicated)

medical student R1 R2 R3 R4 R5 R6 ALL

22. In your opinion, would further "realism" enhance training in the common tasks (navigation, injection, dissection)? Yes No

23. What aspects of the simulator are the most effective?_____

_____

_____

24. What improvements would you most like to see?_____

_____

_____

OTHER COMMENTS_____

_____

_____

APPENDIX J

SUMMARY OF

QUESTIONNAIRE COMMENTS

SUBJECT COMMENTS

The following comments, organized by topic, were collected from the Post Session Questionnaire and notes taken by the proctors during data collection sessions. Not all subjects commented, and redundant comments were omitted from these lists.

WHAT ASPECTS OF THE SIMULATOR ARE MOST EFFECTIVE ?

"Practice in moving through the anatomy with similar tools"

"Instrument movements (jaw movement)"

"Working with instruments in tight quarters"

"The image of the anatomy and the rings to show you the way"

"Learning non-intuitive (i.e. opposite) movements mechanical vs visual"

"Organization of tasks (step to step), hands-on instrumentation, anatomy"

"Anatomy, hand coordination"

"Becoming familiar with endoscopic navigation and anatomy"

"Injection/dissection"

"Liked the fact that the simulator was not 'completely realistic'"

"Navigation/instrument manipulation, simulation of techniques"

"Using training aids, then stepping up to same scenario without training aids"

WHAT IMPROVEMENTS WOULD YOU MOST LIKE TO SEE ?

"Better 3D realism"

"Remove rotational bias of endoscope"

"Haptics on the scope"

"Tool encoder and endoscope shaft interaction needs to be eliminated"

"Less need to stabilize thumb on the forceps tool"

"Improved haptics, improved danger areas -- brain, eye, optic nerve, carotid artery. Improved posterior/anterior ethmoid cells, add thickened mucosa, pus, mucus"

"Blood droplets should disappear instantly and not take too long"

"Audio/Visual warnings for hazards (i.e. arteries, nerves, lamina...)"

"Resistance to "drift" in tool"

"Want an elbow stand for stabilization"

"Place and endoscope 'sleeve' on the scope to allow better grip"

"Allow suction tool to break open ethmoid air cells"

"Better depth perception and better force feedback barrier to instrument drift"

"The 30 degree scope is not right. It still resembles a zero degree scope"

"The view when rotating the 30 degree scope is unrealistic"

"Ability to manipulate mannequin to simulate operative positioning"

"Simulation of complications (entering orbit, penetrating skullbase, etc)"

"Surgical setup (patient position, endoscope sleeve, etc) as realistic as possible"

"Forceps less sensitive/more realistic"

DID YOU FIND THE SIMULATOR LAYOUT REALISTIC, INTUITIVE, CUMBERSOME, UNREALISTIC ?

"Place more consideration on instrument used and instrument handling rather than reality of graphics"

"Moderately realistic"

"Educational, not photorealistic"

"Occasionally had difficulty with both scope and forceps positioning in same location"

COMMENTS ON MODEL 1 (Novice)

"Did not notice heart rate much of the time"

COMMENTS on MODEL 2 (Intermediate)

"Training aids make you concentrate on the aids and not the anatomy, a "distraction"; anteriorly, they're great, posteriorly, needs work"

COMMENTS on MODEL 3 (Advanced)

"The only problem is with the forceps/ bone chips. Simulator too specific where you have to grab bone."

COMMENTS on FORCE FEEDBACK

"Did not really appreciate the force feedback"

"Like the haptics better on than off"

"Want the haptics to 'tear' the tissue, want the ability to feel the biting of the tools"

"It was hard to separate Haptics from intrinsic weight of tool (inertia)"

"Force feedback on stem of instruments and on camera"

OTHER COMMENTS

"I really enjoyed the bloody scope"

"Helps tremendously with hand/eye coordination, anatomy, etc"

"Track respiratory rate and ECG during trials to determine stress level and ability to perform"

"Overall somewhat difficult and frustrating - I felt I had to unlearn some skills developed in real surgery"

"Impressive technology"

"Create a procedure which guides the residents from point A to Z through the procedure. Noticed that the residents tend to pause during the actual procedures because they have no 'plan' to follow"

"A good tool. Would be worthwhile training aid, especially for those learning sinus surgical techniques"