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13. ABSTRACT (Maximum 200
This project involves the development of surgical simulation technology for training military and civilian personnel in management of the abdominal wound. In this context, a virtual reality simulation is being produced using new innovations in computer graphics, physics-based modeling, medical visualization, and tactile feedback robotics. The objective of this effort is develop technology which enables a degree of training not possible using existing technologies in trauma surgery in the battlefield and emergency room.

This effort has produced significant results in several areas. We have continued to advance the computer modeling technology necessary for medical simulation. We have demonstrated interactive models representing both flexible and rigid structures. We have developed techniques for interactive volume rendering of patient specific data. Patient specific visualization technologies will have a significant impact on medicine in the near future. As greater levels of realism are achieved in simulation the computational requirements of the system have expanded. We have developed an expandable architecture that allows for the assignment of multiple processors to each computational task of the simulation system.

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Table of Contents

Introduction

The objective of creating a computer simulated virtual environment for medical training is to provide a level of training not possible using traditional methods. Traditional techniques for teaching trauma procedures have depended largely on the existence of a sufficiently large number of proctors with adequate surgical skills to teach trauma procedures. Other approaches include practice on animals, but animal models of injury often do not reflect human trauma, and raise a host of ethical issues concerning procuring and maintaining animals for surgical training. Also, practice on humans and animals precludes the ability to repeatedly rehearse specific components of the procedure that may prove challenging or require finely tuned motor skills. An additional concern is that Department of Defense (DoD) hospitals are usually not regional trauma centers, so that physicians and allied health personnel in the military may not obtain significant exposure to human trauma cases for training purposes.

Although the airline industry and DoD have used flight and battlefield simulators for many years, several technical challenges have limited the use of computer-based simulation technology in medical education. A flight simulator is easier to implement than a surgical simulator; the terrain of the ground is fixed and rigid, and an airplane simply moves through a path above this terrain. A surgical simulator, on the other hand, is more complex. The terrain of the body (the internal organs) must be interacted with, and they must flex, be able to be cut and then re-attached. This manipulation involves much greater computational sophistication. The organs in the body must be programmed with physiological behaviors and basic principles of physics so they respond appropriately when they are cut, tugged, and stretched. In addition, the surgical simulator must have knowledge of how each instrument interacts with the tissues. For example, a scalpel will cut tissue when a certain amount of pressure is applied; however, a blunt instrument may not– this fact must be simulated.

Simulation of open surgery has always been one of the most challenging problems for anyone developing surgery simulation system. Unfortunately, it has remained an elusive goal, largely considered impossible with the current technology. The biggest challenge, of course, is the fact that surgeons use their hands extensively during surgery to directly manipulate organs and tissue. The human hand is an incredibly sensitive and versatile instrument. To develop a virtual environment which would react realistically to the actions of a hand, and at the same time provide the required degree of haptic stimulation, is simply impossible using today's technology. But just how far have we actually traveled towards that elusive goal? We will try to answer these questions in this paper by describing the HT Abdominal Trauma Simulator (HATS) test-bed. This simulator has been developed for open surgery from the front to remove a kidney that has been shattered as the result of a blunt trauma to the body. At some time during the project it became clear that it would never be possible to model realistically the complex interaction between a surgeon's hands and the contents of the abdominal cavity. The only way it would be possible to train these steps of the procedure was by substituting them with something else which could provide at least some level of cognitive training.

The Solution

Virtual reality technology holds tremendous promise for surgical trauma training, because it offers physicians, battlefield and emergency medical personnel the opportunity to practice in an environment where mistakes do not adversely affect patients. An optimal training simulator accurately replicates the physical and physiological properties of the real procedure. In addition, it offers the ability to automatically track and evaluate performance, provides the option of different procedural scenarios, as well as simulating a range of surgical complications and anatomical anomalies.

Computerized surgical simulations will make a tremendous impact in improving surgical morbidity and mortality. Studies have shown that, for a wide range of diagnostic and therapeutic procedures, doctors doing their first few to several dozen cases are much more likely to make a greater number of errors. Adequate proctoring of learners by experienced surgeons is cumbersome, as there are few surgeons experienced enough in the techniques to proctor their colleagues. It is exceedingly difficult for physicians, particularly those in rural areas, to travel to larger medical centers for training. The requirement also places a burden on experts who could become overwhelmed with proctoring requests.

Because the anatomical models used in the surgical simulator can be based on clinical studies (CT and MR scans), future versions of the proposed simulation could be individualized on a patient basis -- to allow pre-surgical planning and allow physicians to practice difficult operations. Surgical trauma simulators will allow physicians to communicate surgical scenarios with their peers and exchange ideas regarding surgical management of patients. Furthermore, these simulations could be transported to rural areas to allow the dissemination of surgical techniques. Significant operative risk reduction will be made possible by the development of a simulator which would allow transference of skills from the simulation to the actual patient contact.

HATS has become a test-bed for the implementation of a range of different simulation techniques with varying levels of realism and immersion. Some of these can be characterized as multimedia style, while others are full-blown haptics and physics simulations.

Experimental Methods

Most of the early work on simulators for surgery in the abdomen and other soft objects has been characterized by the application of one particular physical model. Cover et al. [5] were the first to present real-time models for surgery simulation. They used a simple surface-based mass-spring model to simulate deformation of a gallbladder. Kuhn, Kuhnapfel et al. [8] have implemented mass-spring models in the KISMET simulation system. Although their models in principle are surface models, they introduce volumetric behavior by including parent nodes that connect nodes on different sides of an object. Surface models are also used in the commercial Teleos software [9] developed by HT Medical, Inc. Teleos uses tubular spline surface models and can model simple structures derived from the tubular topology (e.g. arteries, gall-bladder). Implicitly solved finite element systems have been used in the on-going parallel work of Bro-Nielsen [1,3] and Cotin et al. [4]. These models present a better and faster solution to the deformation problem than mass-spring models. But at the same time they are more complex. See [3] for a discussion of finite element models and their comparison to mass-spring models.

The technology for deforming organs has become quite well understood. There are still a lot to learn, but the available models can solve a range of problems. As a consequence, several realistic simulators have started to appear. Most authors are taking a more systems-like approach to surgical simulation. Sagar et al. [10] have presented an eye surgery simulator using non-linear finite element models to model deformation of an eye. This system is complete with force feedback and allows cutting in the eye. The work of Kuhn, Kuhnapfel et al. [8], which we mentioned above, also represents an interesting system for laparascopic gall-bladder surgery.

In [7], Gibson et al. presented some early results of their effort to develop an arthroscopic knee surgery simulator. This simulator uses a new volumetric approach to model organs. Although this is a promising technique for the future, computers are probably still too slow to allow realistic deformation of a volumetric representation. Recently, Wiet et al. have presented an endoscopic sinus surgery simulator [11] which is based on the use of volumetric models too. A characteristic of both of these simulators is that they operate in a scene that is mostly rigid. The amount of deformation is limited and can therefore be handled with simple and fast algorithms. At HT Medical we have developed a number of simulator systems in recent years, including simulators for neuro-endoscopic surgery, interventional radiology, rigid bronchoscopy, and flexible ureteroscopy. [2] contains a description of these simulators.

The research completed under the DARPA grant have further defined the state-of-the-art in medical simulation. There have been seven primary elements in the HATS research effort. These efforts include the following:

1. Development of haptic feedback interface device
2. Refinement in computer modeling technology
3. Acquisition and processing of polygonal/segmented abdominal anatomy database
4. Development of efficient patient specific visualization algorithms
5. Development of fluid flow simulation model
6. Development of educational content
7. Medical Simulation Software Architecture

Each of these elements is described below in detail with a description of the research methods.

1. Development of haptic feedback interface device

Haptic fidelity is a critical elements to a realistic trauma simulation. Two general approaches have been pursued in the development of the HATS test-bed. One approach, which eventually was determined to show the most promise in terms of adaptability and fidelity, is the use of tactile feedback robotics. The second approach that was researched is a hybrid system integrating robotics, position tracking, proxy physical models, and advanced graphics registration and over-lay techniques.

Approach 1: Tactile Feedback Robotics
The SenSable Technologies Phantom haptic interface device was used to gather 3D positioning input and provide force-feedback. This device provides 6 degrees of freedom for position and 3 degrees of free for force-feedback. Instead of developing the basic force-feedback software, we have used the SenSable Technologies GHOST software package. GHOST implements basic collision detection and force-feedback and we have used it as the basic component in the system for collision detection and force-feedback. Around it we had added intelligent control of models, model complexity, and force-feedback characteristics for deformable models. The final configuration of HATS used the Phantom in conjuction with the CRT display device. This combination demonstrated the greated fidelity and adaptability to a wide variety of anatomic variation and trauma pathology.

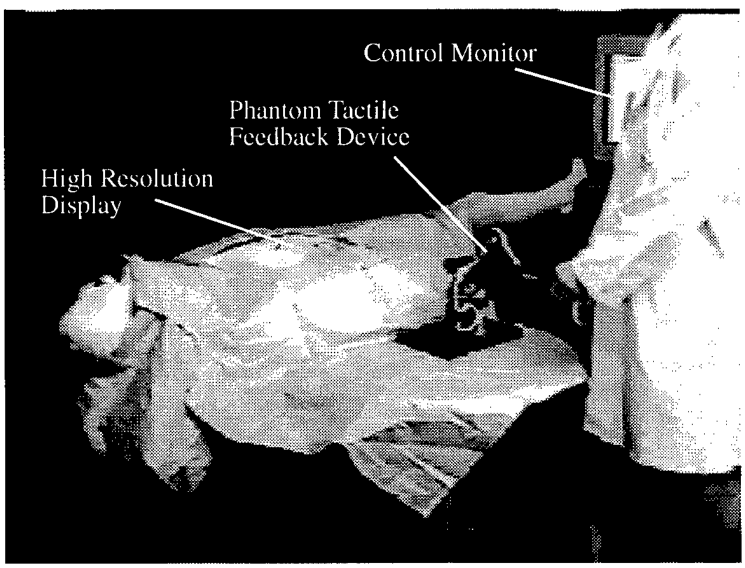


Figure 1. General setup of the HATS simulation system.

A significant number of additional position tracking and force feedback devices were tested prior to focusing on the Phantom system. These devices included the following:

Cybernet Systems six dof force feedback system
Polhemus tracking system
Microsoft force feedback joystick
Immersion six dof tracking probe
Immersion four dof force feedback system
Immersion laparoscopic tracking system
Exos/Marcus force feedback technologies
Bertec co-axial tracking and feedback device

CH Products force feedback joystick
Sensable Technologies Phantoms version I and version II with gimble

Evaluation criterea included tactile resolution, communication protocol issues, dof cability versus HATS requirements, and expandability. The Sensible Technology Phantom device proved to have the higest ratings relative to HATS requirements.

Approach 2: Hybrid Tactile Feedback System
The system used a blue-painted physical model of abdominal organs registered with graphics texture maps derived from corresponding anatomical models derived from the Visible Human database. The user would wear a head-mounted display (HMD) outfitted with lipstick-size video cameras and tracking devices. The physical organs contained sensors that were tracked by the HMD, and the user was able to feel the organs and see his hands interact with visually accurate anatomy.

The research and development of the 'Abdominal Wound Simulator' exploited advanced technology in several areas:

- Computer graphics - models, programming
- Life-like physical models (materials science, special effects)
- Matte techniques - 'chroma key', 'blue screen' compositing
- Motion tracking
- Flexible real-time software architecture

This novel approach, used 'augmented reality' techniques borrowed from the motion picture special effects industry, including blue screen', performance compositing and motion tracking methods.

The technology challenge that required the greatest initial research was in the area of cinematographic special effects. The following section provides a description of 'blue screen' matte methods that were essential for execution of the 'Abdominal Trauma Simulator'.

Blue Screen Imaging: For most applications, creating a blue screen composite image starts with a subject that has been photographed in front of an evenly lit, bright, pure blue background. The compositing process, whether photographic or electronic, replaces all the blue in the picture with another image, known as the background plate. Blue screen composites can be made optically for still photos or movies, electronically for live video, and digitally to computer images. Until very recently all blue screen compositing for films was done optically and all television composites were done using analog real time circuits.

Another term for Blue Screen is Chroma-Key. Chroma-Key is a television process only. A more sophisticated television process is Ultimatte, also the name of the company that manufactures Ultimatte equipment. Ultimatte has been the ultimate in video compositing for many years. With an Ultimatte unit it is possible to create composites that include smoke, transparent objects, different shades of blue, and shadows. Ultimatte now makes software that works with other programs to create digital mattes, called Cinefusion.

Chroma Key: The Chroma Key process is based on the luminance key. In a luminance key, everything in the image over (or under) a set brightness level is "keyed" out and replaced by either another image, or a color from a color generator. Luminance keying works great with title graphics, but not so great for making live action composites. When people need to be keyed over a background image, problems arise because people and their clothing have a wide range of tones. Hair, shoes and shadow areas may be very dark, while eyes, skin highlights and shirt collars can approach 100% white. Those areas might key through along with the background.

Chroma Key creates keys on just one color channel. Broadcast cameras use three independent sensors, one for each color, Red, Green and Blue. Most cameras can output these RGB signals separately from the Composite video signal. So the original chroma key was probably created by feeding the blue channel of a camera into a keyer. This works, sort of, but soon manufacturers created dedicated chromakeyers that could accept all 3 colors, plus the background composite signal and the foreground composite signal. This made it possible to select any color for the key and fine tune the selection of the color. As keyers became more sophisticated with finer control of the transition between background and foreground, the effect became less obvious and jarring. Today's high-end keyers can make a soft key that is basically invisible.

The reason for using the color blue: Red, green and blue channels have all been used, but blue has been favored for several reasons. Blue is the complementary color to flesh tone-- since the most common color in most scenes is flesh tone, the opposite color is the logical choice to avoid conflicts. Historically, cameras and film have been most sensitive to blue light, although this is less true today. Sometimes (usually) the background color reflects onto the foreground talent creating a slight blue tinge around the edges. This is known as blue spill.

Paints and Backings: The standard paints which almost everyone uses are from Rosco, the light gel manufacturer. They make ChromaKey Blue and Green, as well as Ultimatte Blue and Green.

Ultimatte: Ultimatte is a trademark of the Ultimatte Corporation, of Chatsworth CA. It is an outgrowth of work the company's founder, Petro Vlahos, did in the 1960s for the Motion Picture Research Council. The goal was to invent a better matting system for motion pictures. Electronic technology was not ready yet then for a film resolution system, but video could be achieved, and so the first Ultimatte units were created in the 70's.

It is useful to think of the Ultimatte process as a mixing process, not a keying process. This is why it is possible to matte with shadows, hair, water etc. An Ultimatte uses the intensity and purity of the blue signal as a function to determine how much blending to perform between the foreground and background images. Another useful feature of the Ultimatte is the previously mentioned blue spill removal. Other circuits deal with glare, uneven or dirty blue backings, etc. Modern units from the Model V and up can independently adjust the color of the background and foreground plates. An Ultimatte used to have many knobs on its front panel, but the new digital units use a display screen and multifunction controls. A very useful feature is Screen Correction, which allows the operator to create perfect mattes from really bad blue backings. Ultimattes can retain shadows onto the background plate.

Research into the interface device has included solicitation for input from numerous organizations with diverse experience. These organizations included the following:

Physical models:

- Pink House Studios, Inc.
- Fiber-Resin Corp (Full-Flesh™)
- Burman Industries
- Alcone/Paramount Company Inc.
- Mike Maddi (Saturday Night Live - make-up artist)
- Polytek Dept. FX

Animatronics, mechanical FX:

- Animax Designs Inc.
- EFFECTive ENGINEERING

3D Digitizing/Compositing:

- Cyber F/X
- Digital Imaging Systems Inc.
- Photron
- Rhythm & Hues

Motion Capture:

- Tsi
- Oxford Metrics

3D Tracking:

- Polhemus
- Immersion Technologies
- Ascension

We integrated two versions of SensABLE Technologies PHANToM device into HATS. The three motors of the PHANToM are able to replicate high fidelity haptic "images." The PHANToM is limited in it's DOF for active feedback and based on these limitations, we focused our efforts in the second and third quarters of year two on a six-DOF device - The Cybernet, Inc. robot. Our initial demonstrations of the graphic overlay techniques demonstrated feasibility of the graphics overlay technique and integration of a six degree-of-freedom (DOF) force feedback robot with a custom stylus.

Significant limitations of this implementation involved the adaptability of the system to represent variations in anatomy, pathology, and trauma. In addition the component of the system that involved the physical model presented a challenge regarding maintenance and therefor limited it's commercial viability.

2. Refinement in computer modeling technology

For the deformation of surfaces, we have used mass-spring systems (simplified FEM models, see [3]). A mass-spring system consists of a number of vertices with masses, and a set of springs connecting these vertices. In addition, we have added strut springs that anchor the mass-spring surface to a particular default shape and position. When the resulting explicit mathematical problem is solved in real-time, the surface deforms with a physically-based behavior in response to external stimuli. An example of a deforming stomach is shown in figure 3.

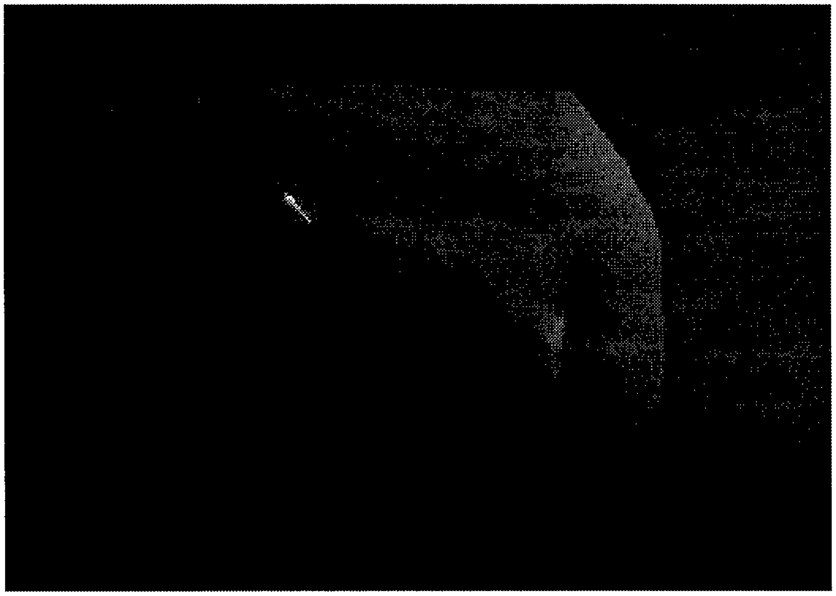


Figure 3. Instrument deforming stomach.

The reason why a more complex FEM system was not used for these surface models, is that they had to be cut to accommodate incisions. This is only reasonable with mathematically explicit models such as mass-spring models (see [3] for a discussion). Cutting is accomplished using a complex set of basic operations applied to individual triangles. Taking into account the range of different cases corresponding to cutting from an edge to another edge, a corner to an edge, the interior of a triangle to an edge, etc. yields a dozen different cases. In each of these cases all the dependencies in the general model have to be updated which is not a trivial task. For arteries and other tubular models we are using a simple linear mass-spring model as the spine of a tubular structure based on connected contours. Each of the contours are linked to a mass-vertex on the spine, and thus controlled by it.

3. Acquisition and processing of polygonal/segmented abdominal anatomy database

We acquired a comprehensive segmented abdominal dataset of the Visible Human male through a subcontract with Visible Productions, LLC, Ft. Collins, Colorado. We have completed initial processing of this data for real-time interaction. This processing included decimation of the models to minimize the polygon count and rendering as solid surface models. On the Silicon Graphics Infinite Reality system we achieved frame rates of approximately five frames per second on the complete dataset without culling or other processing techniques. The process of decimation of this dataset provided to be laborious and eventually we adopted a technique using the original dataset from the National Library of Medicine and M-Vox (Bro-Nielsen) software for segmentation.

4. Development of efficient patient specific visualization algorithms

The availability of hardware with advanced 3D graphics features opens the door to new kind of applications and provides new power to algorithms that were not before applicable in interactive applications. One of the most interesting feature now available on the new generation Silicon Graphics workstations is the ability to define volumetric textures. A volumetric texture is a 3D region where texture values are stored in a three dimensional grid. Each polygon inside the volumetric texture assumes the texture values it intersects. This graphics feature provides a new way to apply interactive algorithm for Volume Rendering resulting in fast rendering updates. Our technology allows anatomical visualization of patient specific and Visible Human volume data explicitly (rather than through a mind's eye view).

These volume visualization algorithms allow display and analysis, interactively of volumetric data from CT or MRI scanners and full color data set (the Visible Human data). The software runs on workstations from Silicon Graphics (High and Maximum IMPACT) and on Onyx Reality Engine and the new Infinity Reality. Features include infinite and interactive point of view, with arbitrary section planes.

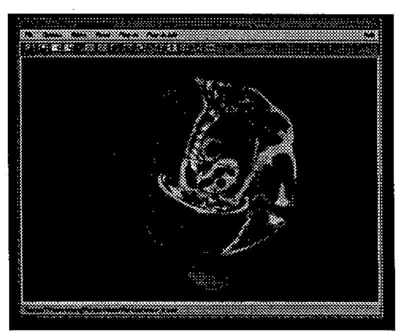
It is anticipated that the technology will integrate with haptic input devices, allowing the user to feel the data as a real object. Feasibility has been established in the identification of approximate tissue density, as derived from gray scale and color data and assignment of tactical feeling to volume data. This will open the door on surgical simulation directly on patient data without any kind of computational expensive transformations. Research is continuing to allow interactive volume deformation and cutting.

Capabilities include the following:

- Full support of gray-scales (MR/CT) and color data.
- Resolution up to 256x256x384 voxel in interactive frame rate
- Interactive manipulation of point of view
- Interactive advanced look-up table manipulation to select different kinds of tissues
- Arbitrary clipping plane to inspect internal structures
- Interactive scaling of models and brick explosions
- Depth resolution ranging from 1 to 1,000 polygon planes

This technology has been incorporated into a tool set for the medical visualization industry in a product called TELEOS Voxel Visualizer™ (T-Vox™). Much of the algorithmic research for this code has been accomplished through this DARPA grant. The refinement of this software as a product, was supported by HT Medical's cooperative research agreement with the US Department of Commerce's Advanced Technology Program.

T-Vox is interactive volume visualization software for real-time rendering of any 2D sequential medical data. T-Vox supports data from both gray-scale (MRI, CT, and 3-D ultrasound) and color (Visible Human Data Set and confocal microscopy) sources.



T-Vox™ 1.0, the industry's fastest volume rendering software, was launched at the Medicine Meets Virtual Reality (MMVR) conference in San Diego, CA, January 22, 1997.

The software also has an expandable plug-in architecture for the development of custom options. Plug-ins available for purchase with T-Vox 1.1 include: T-Views - Generates animation files in MPEG or QuickTime formats. Includes unlimited numbers of cameras and animation steps. T-Explorer - Positions the camera precisely where the user wants it. Works in conjunction with T-Views to precisely generate a key frame for fly-through animation and virtual endoscopy. T-Reports - Generates HTML documents to be shared on an intranet or the Internet. Perfect for communicating results and generating archives of studies. T-Analyze - Easily imports ANALYZE data files.

5. Development of fluid flow simulation model

Realistic fluid flow has been a significant challenge for real-time simulation. Two different techniques were developed to allow for intravascular flow and flow through a hemorrhage or cut. We initially developed intravascular fluid flow models based on ramp constrained random flow of color values. Variations of the ramp constraints were used to control the viscosity of the fluid. This technique has proved to be adequate for visualization, but limited in its ability to have physical and physiologic impact that replicates the true properties of the liquid. Our current methodology, which has now been implemented and incorporated into our interventional radiology simulation system, is based on computational nodes of fluid automata. This technique allows for realistic models of diffusion and pressure to be incorporated into the simulation system and for changes in intravascular flow to result in systemic changes.

We have implemented a bleeding algorithm that uses a diffusion-style algorithm to model the flow of blood on the surface of polygonal models. For performance and complexity reasons the blood is stored only at the vertices of the polygonal surface. This limits the precision of the blood movement to the distance between polygon vertices, but allows the cutting algorithm to be used on the bleeding surface as well. In addition to modeling the flow of the blood, the algorithm also modifies the polygonal surface using a bump-mapping approach to provide the illusion of blood lying on top of the polygonal model. At rendering time a vertex with blood on it is moved in the normal direction of the surface. The distance is determined based on the amount of blood on the vertex.

6. Development of educational content

A set of storyboards was developed that showed the surgical approach in detailed steps. These storyboards were very useful both in terms of guiding the development of the technical systems for the simulator and also as the basis for multi-media guidance during the simulation. Some of the steps in the procedure are difficult or impossible to model realistically. Instead we had to substitute some of the training steps with different degrees of non-immersive simulation.

A general description of the procedure is described below (adapted from Taylor, D.L. and W.R. Fair (1985))

Major indicator of serious complications: Loss of continuity of the renal capsule and distraction of fragments.

If visualized or suspected, major perirenal hematoma indicates the necessity for opening of the retroperitoneum and exploration of the kidney. In the emergency setting, injudicious exploration may lead to unnecessary nephrectomy, however, several studies have shown the first 2-3 days offer the best window of opportunity for corrective surgery.

Surgical approaches:

(1) Make a vertical midline incision in the abdomen.

(2) Begin exploration of the abdomen, following establishment of hemostasis - include debridement of the path of any penetrating object(s) or missile(s). The retroperitoneum is approached along the aorta at the root of the mesentery.

(3) If you find the existence of a large retroperitoneal hematoma or other indications of a major renal trauma, open the retroperitoneum medial to the inferior mesenteric vein and identify the aorta.

Indications for surgical exploration of major trauma (McAninch and Carroll (1989)):

- Expanding or uncontained hematoma
- Pulsatile retroperitoneal hematoma
- Major urinary extravasation
- Non-viable renal parenchyma (loss of more than 15% of the kidney)
- Vascular injury

Please note that some of these indications can only be determined using pre-operative imaging methods, which may not be practical in a battlefield setting.

(4) Dissect cephalad along the anterior surface of the aorta to expose the left renal vein crossing the aorta.

(5) Vascular control is obtained by clamping the renal vein and artery at their origins from the vena cava and the aorta. (mistake possible here - if the surgeon strays too far cephalad and lateral to the aorta, the splenic artery and vein may be mistaken for the left renal artery and vein).

(6) Reflect the colon prior to exploration of the retroperitoneal space.

(7) Use the principles of exploration outlined by Scott and Carlton and their colleagues (Scott, Carlton, and Goldman (1969); Scott and Selzman (1966):

- Obtain early vascular control
- Debride any devitalized tissue
- Obtain hemostasis by suture ligation
- Insure watertight closure of the collecting system
- Approximate the parenchymal margins
- Obtain extraperitoneal drainage of the renal fossa

(8) Analysis/corrective surgery of the kidney:

Substantive damage limited to a portion of the kidney usually indicates partial nephrectomy.

Disruption of the collecting system usually occurs through damage to the calyceal fornices. This repair involves watertight suturing of the collecting system at the level of the fornix.

If bilateral renal damage is present, the kidney with the best possibility of recovery is repaired first.

Transcapsular damage is often present in major renal injuries, especially those with penetrating injuries (eg, bullets, shrapnel; see Scott, Carlton and Goldman (1969)). In these cases:

- Ligate all major vessels.
- Use a watertight closure for the collecting system.
- Close the capsule with running or interrupted sutures.
- Use diverting pyelostomy for clots in the renal pelvis.
- Make sure that all devitalized tissue is debrided.

7. Medical Simulation Software Architecture

The software for the simulator has been built as a multimedia system with VR simulation, Patient records (GUI), and Training instructions and guidance (GUI) (see figure 2). The latter two components are contained in a Graphical User Interface (GUI) that has the appearance of the standard manila folder used by many American medical institutions to store patient information. The GUI is shown in figure 3.

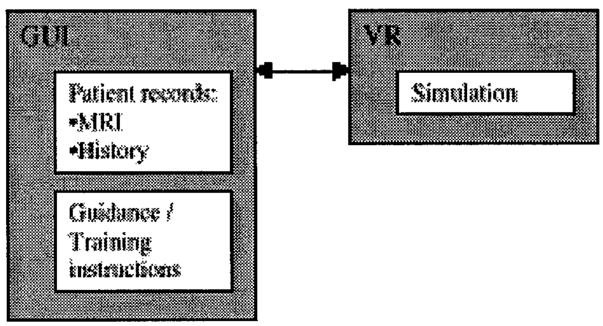


Figure 2. Multimedia framework

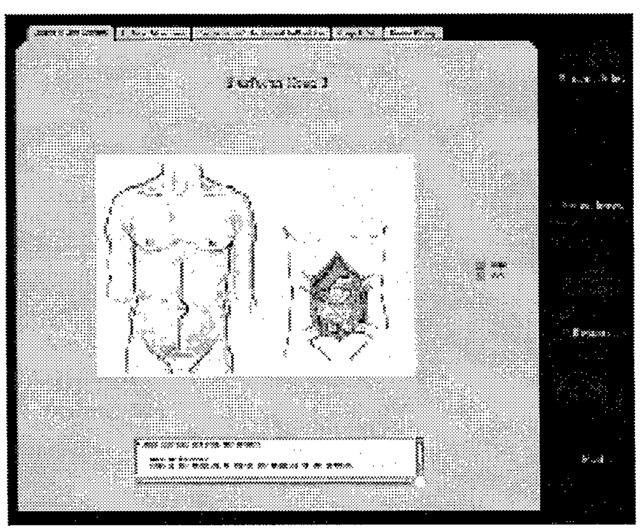


Figure 3. Graphical User Interface.

Because of the computational load of this sort of simulation system, the software has been developed as a real-time distributed software system designed to run on different computers linked with an ethernet. The software contains at least six independent software processes that take care of different components of the simulation. We analyzed the communication between the different processes and found that the best way to divide the processes was by putting haptics and collision detection on one computer, and the remaining processes on another computer - both having shared memory between their respective processes. In practice a four processor SGI ONYX-2 shared memory parallel processing computer served as the main platform and a SGI IMPACT as an additional compute server. To implement the communication between the two computers we used the Parallel Virtual Machine (PVM) [6] communication protocol. The system diagram is shown in figure 4.

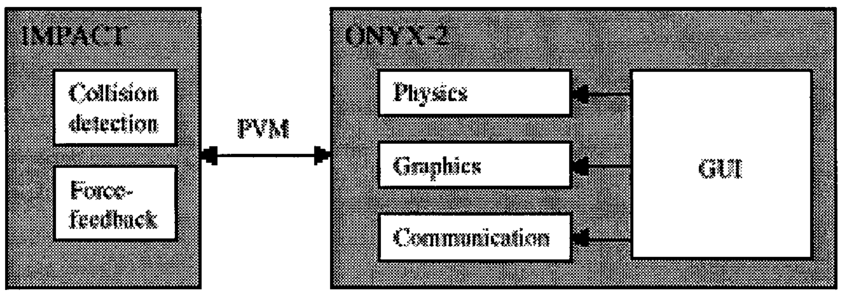


Figure 4. Processes on the two computers.

7. Conclusion

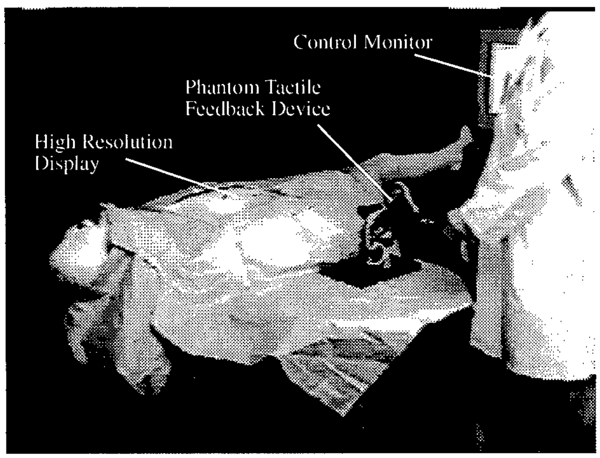
We have developed a surgical simulation test-bed for training the removal of a shattered kidney by open surgery from the front of a trauma patient. This kind of surgery is particularly complex and difficult to simulate, and the simulator cannot be characterized as being fully realistic. With current computers and technology it is not possible to develop completely life-like simulators for open surgery. But developing the test-bed has allowed us to study the interaction of a number of different technologies for deformable models, cutting, bleeding, haptic modeling, interprocess communication, and multimedia interfaces. The simulator includes some of the newest advances in deformable models and related technologies. Throughout the research period these technologies have been leveraged toward the development of other simulators at HT Medical Systems. The technologies focused on six areas including:

1. Development of haptic feedback interface device
2. Refinement in computer modeling technology
3. Processing of a large deformable polygonal database
4. Development of efficient patient specific visualization algorithms
5. Development of fluid flow simulation model
6. Medical Simulation Software Architecture

Each of these areas was developed with a goal of re-usability toward other medical simulation applications. The following section describes the results from each technical area and then includes examples of additional applications developed by HT Medical which have leveraged this technology development.

1. Development of haptic feedback interface device

The link between the human sensory and motor systems and the computer can be either a barrier to effective simulation and training or a natural conduit through which information and experiences flow. With the advent of realistic simulations and computerized training software the missing link has been the ability of the clinician to "feel" and physically interact with the patient's anatomy, both externally and internally. Although research in this field has been going on for 20 years or more, developments in computer chips, motor technology and programming interfaces, even though greatly spurred by other markets such as the interactive entertainment industry, have not yet made this technology accurate or inexpensive enough to be widely useful in medical simulation and training.



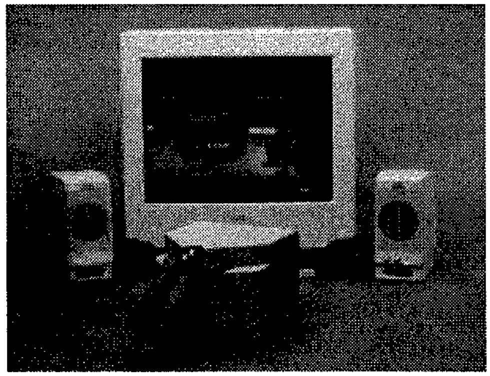
HATS with Phantom tactile feedback device

Our objective with this interface device development research has been to provide realistic feedback (force and/or otherwise) to a physician performing surgery. The requirements for the specific procedure being simulated has a major impact on the specifications for the tactile feedback interface device. Open surgery simulation, such as abdominal trauma surgery which requires direct, between the fingertips, interaction, requires a level of proprioceptive sensation that is beyond the current state-of-the-art in haptic technology. Procedures involving the manipulation of an instrument such as a scaple is possible with the use of exisiting technologies including the Sensible Technologies, Phantom.

Lessons learned throughout the three years of this research program in tactile feedback have been intregrated into a number of interface devices for HT Medical's simulation products and prototypes.

A class of nursing students with HT Medical's CathSim™ simulator with AccuTouch™

Cathsim™ represents the basis of HT Medical's vascular access product line. It consists of the AccuTouch™ tactile feedback interface device, and software modules providing educational content for catheter insertion procedures.



The CathSim™ I.V. training simulator with AccuTouch™ tactile feedback interface device

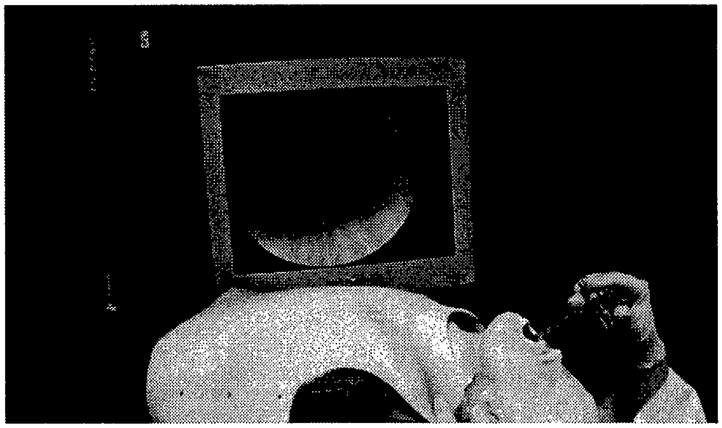
CathSim is a Microsoft Windows compatible product. This product was launched in January 1998 targeting nurse training institutions. Additional modules are under development for the placement of a central venous catheters, PICC lines, and other catheter related procedures.

The PreOp™ endoscopic simulator allows realistic manipulation of a proxy flexible endoscope

2. Refinement in computer modeling technology

Several advances in modeling technology have resulted from this research. Refinements in collision detection, specifically involving deformable objects has been a major challenge in medical simulation. Two factors have facilitated acheivment of our goals in this area; implementation of software techniques (fast-finite elements, spline-based modeling, and on-the-fly polygonal decimation routines) as well as the concurrent and ongoing improvements in graphics accelerated hardware including the availability in 1997 of the Silicon Graphics Onyx Infinite Reality workstation.

Results from this work have been leveraged across several of HT Medical's simulation systems. HT Medical is developing a Flexible Bronchoscopy simulator with the partnership of pulmonologists and pharmacology experts at Merck & Co. This procedural simulator allows for examination of the primary, secondary, and tertiary branches of an adult bronchus modeled from the Visible Human Project data.



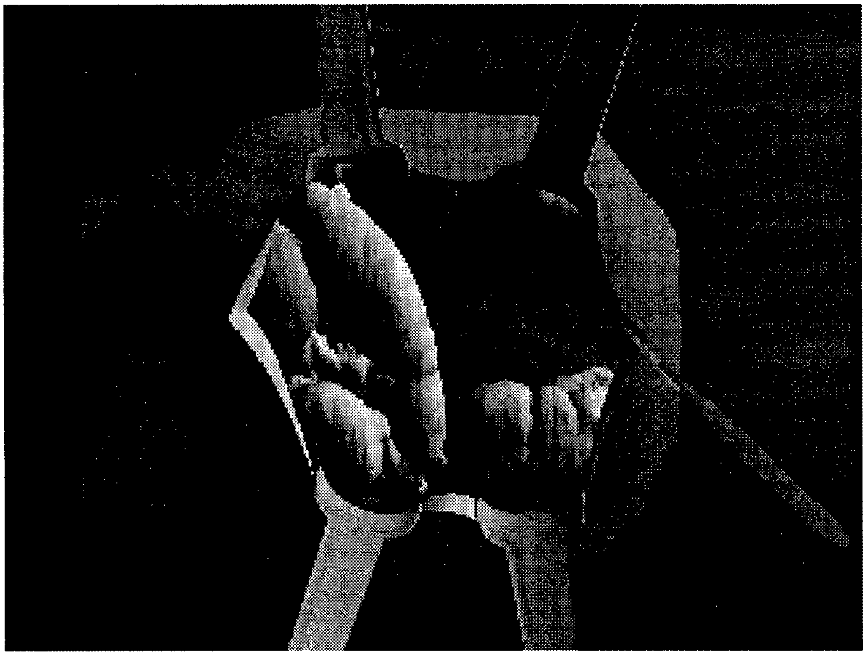
HT Medical's pediatric ridged bronchoscopy simulator with content developed in collaboration with Penn State's Hershey Medical Center.

HT Medical has completed a Pediatric Rigid Bronchoscopy Simulator in collaboration with Penn State's Hershey Medical Center (HMC). Based on preliminary quantitative evaluation, HMC concluded that virtual reality training at their teaching hospital could tremendously reduce their OR-based training time and costs. HT Medical's bronchoscopy simulator was the first of several training simulators for HMC's "Virtual Operating Room." The simulator includes case history and associated material for the pediatric case and allows use of a range of actual rigid scopes to diagnose subtle abnormalities.

In addition, HT Medical has designed a virtual Neuroendoscopy simulator, funded in part by Johnson & Johnson Professional - Codman, for exploration of the ventricular system of the central nervous system. The user is able to navigate throughout the ventricles using an endoscopic device threaded through the top of a mannequin. HT Medical has also developed simulations in the areas of Ureteroscopy and Laparoscopy.

3. Processing of a large deformable polygonal database

The large number of deformable objects within the environment of an open abdomen required the development of several techniques for developmeing and managing the database. Intiatially it was believed that the all objects within the interactive environment would be active throughout the complete simulation. The processing capability of the multiprocessor graphics supercomputers still required the segmentation of the procedure into component parts - procedural task steps - that could be active. This segementation solved a computational bottle-neck and also worked within an empirically effective educational design.



HATS stomach after initial incision has been performed

Further validation of the large database manipulation techniques were provided through several demonstration projects completed in collaboration with Glaxo Wellcome and with Boehringer Mannheim.

Large anatomical databases have been displayed using techniques developed for the HATS research and have been explored by thousands of physicians at several international conferences

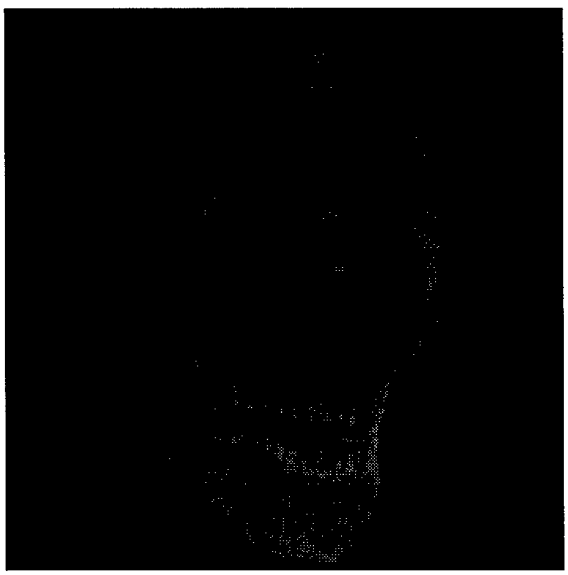
With Glaxo Wellcome, HT Medical created an Upper G.I. Fly-Through Game called VR Endoscopic Challenge. The Endoscopic Challenge is a virtual reality 'fly-through' of the esophagus. Visitors 'pilot' a virtual endoscope and must target erupting acid as it makes its way up the esophagus. The goal is to reduce acid contact time and to relieve heartburn pain due to reflux disease. The purpose of the program was to attract physicians to the Glaxo Wellcome booth during Digestive Disease Week, May 1996.

Ischemic Insult - At the 1996 American College of Cardiology (ACC) Conference, HT Medical debuted a virtual reality "fly-through" simulation, called Ischemic Insult, involving the heart and great vessels. This simulation focused on treatment for acute myocardial infarction. The simulation allows doctors to experience first-hand how to open up blocked arteries that cause heart attacks. Wearing a head mounted display (n-vision), physicians feel as if they are being miniaturized and injected into the heart's left atrium. Their mission, in order to save the patient, is to maneuver through the chambers of the heart and arteries, find the blood clot, and destroy it - in three minutes or less.

4. Development of efficient patient specific visualization algorithms
Patient specific volume rendering at interactive frame rates is now possible with HT Medical's Teleos Voxel Visualization (T-Vox™) software. This software is now in use by customers at many of the world's leading academic and medical research facilities.

Capabilities include the following:

- Full support of gray-scales (MR/CT) and color data.
- Resolution up to 256x256x384 voxel in interactive frame rate
- Interactive manipulation of point of view
- Interactive advanced look-up table manipulation to select different kinds of tissues
- Arbitrary clipping plane to inspect internal structures
- Interactive scaling of models and brick explosions
- Depth resolution ranging from 1 to 1,000 polygon planes



Interactive T-Vox™ rendering of the segmented skull from the Visible Human Database

5. Development of fluid flow simulation model
Models were developed for both intravascular and extravascular fluid flow. Realism in bleeding never fully achieved the same level of fidelity as other elements of the visual simulation. The core methodology of particle-system modeling when implemented as a particle stream or as the basis for an isosurface rendering is limited in either the number of particles that can be rendered in real-time in the first case or the computational expense of the latter. Some representations of bleeding with the use of texture maps and clipping planes provides a high degree of visual realism for certain types of bleeding. Implementation of appropriatly creative graphics "tricks" is still needed in many specific applications of extravascular flow.

We have acheived a very high level of fidelity in simulation of endovascular flow. The techniques developed have been integrated into interventional flouroscopy simulations with striking realism.

HT Medical's simulation of endovascular flow of contrast media is difficult to differentiate from actual flouroscopic imaging of live patients.

HT Medical is developing the PreOp Endovascular Simulator to train clinicians in procedures such as balloon angioplasty and stent placement. This system, which duplicates the look and feel of the actual procedure, enables clinicians to practice procedures as many times as necessary before performing the procedure on a patient.

The simulation also integrates pharmaceuticals and devices used in the actual procedure - such as thrombolytic agents, contrast media, catheters, sheaths, guide wires, and stents. The simulator incorporates tactile feedback so that clinicians manipulating these devices can "feel" sensations experienced during procedures, such as encountering an unexpected obstruction in the artery.

HT Medical unveiled the prototype for this system at the 1996 meeting of the Society of Cardiovascular and Interventional Radiology (SCVIR) and is currently preparing the system for routine use.

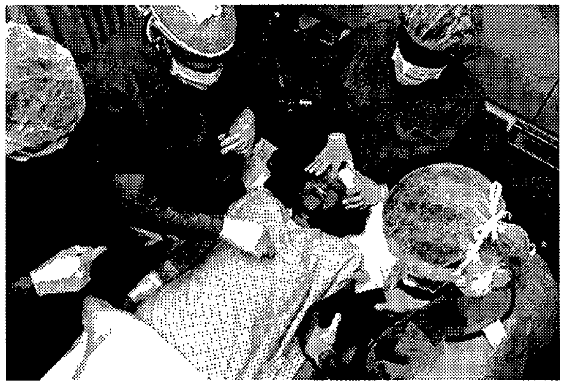
6. Medical Simulation Software Architecture

The software architecture issues for medical simulation center on the multiple time-critical computational tasks including processing of graphics, physics, multimedia elements, and tactile feedback. The complexity of HATS necessitated the development and implementation of a comunications protocol called Parallel Virtual Machine (PVM). PVM segmented the computational tasks into collision detection and force feedback on a single processor SGI Impact computer while the physics, graphics, and communications tasks were distributed on a four processor SGI Onyx2 system.

PVM allows the multi-thread computational processes to occur while maintaining real-time interactivity. Lessons learned during the implementation of PVM have been integrated by HT Medical in several other medical simulation systems. HT Medical's CathSim™ system allows realistic feel of needle insertion while graphics performance remains at near thirty frames per second on an off-the-shelf Windows-based Pentium II single processor computer.

Discussion

Cost containment programs are, and will continue to be, an integral part of health care delivery systems throughout the world. At the same time there is an absolute need to maintain, and in some areas improve, the quality of care that can be provided.



Current training relies too much on patient contact, resulting in high costs to the healthcare system and less than ideal clinical outcomes

The technologies have now evolved to the point where medical simulation and imaging is both credible and cost-effective for training, objective evaluation of practitioner competence, and patient-specific interventional planning. Within the healthcare industry it is well accepted that simulation technology will be a significant addition to current pre-operative planning standards.

Simulators improve training, reduce costs, and limit patient risk

Many medical procedures are especially suited to computer-based simulation for training and certification, because they already place the physician remotely from the site of the operative manipulation. Current medical procedures dependent upon remote manipulation of medical devices and viewing from video monitors provide an easy transition to the simulation environment. We can use the historical experience and commercial success of flight simulation as a paradigm, yet the physician population represents more than ten times the number of commercial airline pilots. Based on the number of physicians and the millions of other allied healthcare providers, medical simulation represents a significant market opportunity.

Medical simulators allow healthcare providers to practice procedures in an environment where mistakes do not have dire consequences, lowering risk associated with training on human patients, avoiding the use of animals for training, and establishing standards and optimization of specific procedures.

The availability of simulation products will have a significant effect in medical cost reduction, reduced reliance on animals, and most importantly, the availability of an effective training tool will signficantly aid in appropriate utilization of medical devices and will improve clinical outcomes.

Specific examples are as follows:

Reduces Complications

Improved training will result in fewer complications. Just as the LINK simulators in the 1940s reduced fatal crashes during night aircraft carrier landings by 95% during World War II, medical simulators will reduce errors and save significant costs associated with those complications. Simulation could bridge the gap between the number of actual cases performed by a practitioner and the total number of cases needed to maintain skills.

Example: A study from Duke University (Jollis, J.G. 1996) showed an increase of significant complications of 2 per 100 coronary angioplasty procedures between high and low volume clinicians. There are approximately 1,300 interventional cardiology clinics in the U. S.. A typical institution with four cardiologists performs 160 angioplasties per year. Best results are obtained by individuals performing at least 150 each. Complications can result in the need for open surgery at a cost of $30,000 per patient. Saving potential is 160 x 0.02 x $30,000 = **$96,000 per year per clinic** or **$125 million** nationally for angioplasty.

Litigation

Simulation could provide evidence that adequate training is provided within an institution and using the simulator as a scoring device allows healthcare providers to demonstrate competency. In December of 1997 a Connecticut jury awarded $12.2 million to a physician, who as a resident at Yale Medical School, was infected by AIDS due to inadaquate training in catheter placement technique (New York Times, December 21, 1997). Use of HT Medical's CathSim™ Intravenous Training System may have prevented this injury and subsequent liability.

Increase Utilization of New Medical Procedures

The availability of in-house training and skills maintenance enhances comfort with new medical products and increases utilization by a conservative estimate of 20%. As many as 70% of graduates from animal and cadaver courses do not adopt the procedures in their practice because they have not been comfortable with the amount and/or quality of training.

Reduced Operating Room Time

With resident training the learning curve would be accelerated through simulation.

Example: The American Heart Association (AHA) guidelines for coronary angioplasty state that residents require 200 procedures to be at the top of the learning curve. Training adds approximately 30 minutes to each procedure. The cost of operating room time is typically $1,500 per hour. Saving potential is 200 x 0.5 x $1,500 = **$150,000 per resident** or **$3 billion** nationally.

Reduced Use of Animals

Computer-based simulation technology will replace and augment current models with the additional benefits of anatomic accuracy that can not be obtained with animals; pathology and dynamic properties not possible with human cadavers; and without the consumption of expensive medical devices.

A typical training program for new imaged guided medical procedures requires two days and between .66 to 1.0 animal per physician. Each animal costs $2,500. HT Medical will eliminate the need for animals during the first day of the training program. This proposed system will save half the animals currently used.

Reduced Waste of Medical Devices for Training

Simulation is non-destructive to medical devices. A typical department of a teaching hospital has two interventional radiology fellows per year doing 100 procedures involving stent deployment. Stents cost upward of $1,000 each. Approximately 10% of stents are wasted during the learning curve. There are approximately 1,000 teaching hospitals in the U. S. Saving potential is 100 x 0.1 x $1,000 = **$10,000 per year per hospital** or **$10 million** nationally.

Improves training

Using simulation-based virtual environments for medical training, it is possible to teach healthcare providers more thoroughly than current approaches. The use of medical simulators has precedence in the training of commercial and military pilots where the quality and depth of training has improved and cost decreased through flight simulation trainers. With modern aircraft, flight training would be impossible without simulators. The same can be anticipated for future medical practices.

Localizes Training

Simulation systems will eliminate many costs associated with the traditional training at remote sites and will limit revenue losses due to absence from the medical facility during training. Hospitals and clinics that have simulation systems will have immediate access to new device training.

Standardizes Training and Certification

Simulations will generate more consistent and predictable patient outcomes and will lower complication rates. Standardized care is a central focus in the managed care environment. Hospitals and HMOs will use these systems to objectively measure cognitive and, for the first time, motor-skills. There is pressure from organizations like the American College of Cardiology, the American College of Surgeons, and insurance providers for hospitals to use simulators, when they become available. Simulations will, in the near future, be used to establish that physicians have the requisite skills, prior to patient contact.

Provides Skills Maintenance

Skills maintenance will be available without large patient volumes. Patient referrals to larger medical facilities will be reduced - saving money in travel and time from work for patient.

Safety

Ability to practice fluoroscopy in an environment without exposure to x-ray radiation - standard training involves use of a real fluoroscope. A wide variety of medical techniques will be simulated that could not otherwise be safely and ethically tested and taught without simulation. In addition, HT Medical's systems provide the ability to rehearse a variety of procedures without risk of exposure to infection.

These large financial benefits of simulation provide an opportunity to satisfy a commanding imperative of the healthcare industry for cost containment by supplying cost-effective virtual reality training products.

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11 A. Personnel Receiving Pay From this Effort

The following HT Medical Systems, Inc employees received pay from this effort:

J.	Ackerman	O.	Brand
J.	Bilman	M.	Bro-Nielsen
H.	Connacher	J.	Cordova
R.	Cunningham	P.	Feldman
W.	Glass	M.	Giffhorn
D.	Helfrick	G.	Higgins
M.	James	C.	Kramme
J.	Lagomarsino	S.	McCarthy
M.	McGurn	S.	McMillan
D.	Meglan	G.	Merril
J.	Merril	A.	Milman
G.	Moussazadeh	B.	Nguyen
R.	Raju	E.	Ross
P.	Sherman	S.	Swamy
R.	Stacey	R.	Waddington
T.	Walderman	J.	Whitley
M.	Ursino	X.	Zeng

Consultants, Sub Contractors, and Vendors:

SRI	Voxcam Associates
Creative Desighn Services	Rob Johnston
Fred Thaheri	Howard Champion (Tech Med)
Son Ly	Pierre Chastanet
Stephen Wylam	

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Recent Invited Presentations

- "Use of the Visible Human Data in Medical Simulation" Invited presentation to the National Library of Medicine's Board of Regents, Bethesda, MD, January 28, 1998.

- "Virtual Reality Technology to Train Healthcare Providers in More Complex Procedures" Medical Data International concurrent session with the Annual Meeting of the American Heart Association, Orlando, FL, November 11, 1997

- "Medical Visualization and Simulation" Guest speaker for the Silicon Graphics European Medical Visualization Workshop, Brussels, Belgium, November 4, 1997.

- "Innovations in Volume Rendering of Visible Human Data" presentation at the National Museum of American History, Washington, DC, October 19, 1997.

- "Applications of Information Technology to Biomedicine: Medical Simulation and Robotics" Broadcast of the University of Maryland's Instructional Video Network, Baltimore, MD, October 15, 1997.

- "VR and Medicine" plenary talk, Medical Data International's Emerging Medical Technology Conference, Crystal City, VA, September 29, 1997.

- "Medical Virtual Reality, a Status Report" plenary talk at MEDTEC '97, Vienna, VA. August 17, 1997.

- "Info Tech and Medicine...The Revolution Starts Here" Keynote Address, International Technology in Health Education Conference, Plattsburgh, NY. June 12, 1997.

- "Virtual Reality's Roles in Medical Device Design" speaker annual Medical Design & Manufacturing conference, New York, NY. June 3, 1997.

- "Virtual Reality Surgical Simulation" The Keynote Address for the annual meeting of the Association for Surgical Education, Philadelphia, PA. April 9, 1997.

- "The Virtual Reality Showcase" Radiological Society of North American, Chicago, IL. December 1-5, 1996.

- "Virtual Reality in Medicine" Plenary talk at the Fall meeting, The Society of Surgeons of New Jersey, Morristown, New Jersey. November 6, 1996.

- "Virtual Reality Applications in Interventional Radiology and Beyond" Cook Europe International Conference, Copenhagen, Denmark. October 29, 1996.

- "Reassignment of Physical and Physiological Attributes to the Visible Human" Plenary speaker, National Library of Medicine's Visible Human Conference, Bethesda, MD. October 7, 1996

- "Using Virtual Reality and Simulation Technology to Revolutionize Procedural Medical Education" Maryland Bioscience Forum, College Park, Maryland. September 16, 1996.

- "Virtual Reality Applications for Infusion Therapy" plenary presentation for the World Wide Clinical Symposium III, Deer Valley Utah. September 9, 1996.

- "Employing Virtual Reality to Simulate Medical Procedures: Using Everything from Nintendo Games to Super Computers" plenary presentation of the Conference of Interactive Technology in Health Education, Plattsburgh, NY. June 13, 1996.

- "State-of-the-Art in Laparoscopic Simulation" presentation to the Executive Committee of the Society of American Gastro Endoscopic Surgeons, Norwalk, CT. July 30, 1995

- "Virtual Reality and Medicine" Keynote address, InfoHealth '95. Sao Paulo, Brazil. July 4, 1995.

- "Interactive Multimedia: New Applications and Trends -- Virtual Reality and Medicine" invited lecture for Johns Hopkins University School of Continuing Studies. November 3, 1994.

- "Virtual Reality Applications in Medical Training and Pre-Operative Planning" International Symposium on Medical Imaging, George Washington University Medical Center. June 17, 1994.

- "Computer Simulations of Biological Systems" presented at the International Conference of Computer-Assisted Imaging of Embryonic and Fetal Development, sponsored by the National Institute of Child Health and Human Development, National Institutes of Health. June 23, 1994.

- "Virtual Reality Applications in Medical Visualization" Invited lecture to the Australian medical visualization research community. Sydney, Australia. September 15, 1994.

- "Virtual reality laparoscopic surgical simulation -- pelvic lymph node dissection" Presentation at the International Urological Society Conference. Sydney, Australia, September 16, 1994.

- "Medical Education Applications of Virtual Reality" 66th National Meeting of the American Health Information Management Association (AHIMA), Las Vegas, Nevada, October 23, 1994.

- "Virtual Reality" Session Leader, FOSE Conference, Washington, DC March 23, 1994.
- "Developments in Virtual Reality and Broadcast Television" Address to The National Academy of Television Arts and Sciences. Bethesda, Maryland. February 16, 1994.
- "Virtual Reality & Education: Today's Supercomputer is the Video Game Machine of Tomorrow" Keynote address, MICROTRENDS '93, The International Communications Industries Association. Orlando, Florida June 27, 1993.