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U.S. Market for Virtual Reality in Surgery & Imaging, 2004-2009

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SAMPLE CONTENT

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SECTION 3: VIRTUAL REALITY SYSTEMS IN SURGICAL TRAINING

The advent of imaging systems that would allow surgeon to see inside the body has revolutionized the field of surgery. In many surgical specialties, it is no longer necessary to perform open procedures; instead most surgeons opt for minimally invasive surgery (MIS). MIS relies on miniaturized video cameras, a video display, and a few revolutionary surgical tools. Among the first MIS procedures to be performed was the removal of the gall bladder through a small incision in the abdominal wall. Other small abdominal incisions were made for inserting the camera and illuminant, and additional surgical tools. The procedure, called laparoscopic cholesystectomy, is performed by dexterously maneuvering long, slender tools that cut, clamp, and suture anatomical structures within the abdominal cavity. The surgeon, viewing the effector end of the tool on the video screen, explores and manipulates internal organs.

While MIS has added “X-ray” vision to the surgeon’s armament, allowing him to visualize tissue color, perfusion, and texture, it has largely deprived him of the sense of feel that open surgery provides. The surgeon’s sense of touch – his haptic sense – enables him to identify otherwise obscure tissue boundaries, to differentiate normal and abnormal tissue, and to determine the appropriate amount of force to use in cutting, clamping, and suturing. In MIS, the surgeon is deprived of “hands-on” tactile experience, and so must interpret tool/tissue interactions at a distance – from the proximal end of the slender tools that he has inserted into the abdomen. Thus, surgeons must acquire a new sense of touch for performing laparoscopic surgery, and that acquisition requires additional training to improve haptic sensorimotor skills.

Training for laparoscopic procedures – minimally invasive surgery simulation and training (MISST) – is the province of haptic-intensive simulation. A number of companies, identified in the accompanying exhibit, have developed laparoscopic simulation systems based on haptic interfaces that enable the surgeon to practice MIS skills outside of the operating room. Haptic simulation involves several elements – haptic interfaces, haptic rendering, haptic recording, and haptic playback – that have been incorporated into existing MISST devices to a greater or lesser extent.

Haptic interfaces are evolving from the electro-mechanical training boxes that are little more than laboratory prototypes to sophisticated devices that incorporate real laparoscopic instruments and simulate the patient's external an internal anatomy.

Haptics rendering has also evolved in recent years to include not only collision detection, but realistic force-reflecting tissue responses. The former provides the user with information that he has contacted the virtual organ, for example; while the latter provides tactile information about the response of the virtual organ to palpation, clamping, and suturing. These distinctions are important when considering that MISST involves two classes of effectors: long slender probes for palpating, puncturing, and injecting; and articulated tools for grasping, retracting, gripping and cutting soft tissue.

During simulations, the trainee views virtual models of the 3D surface of target tissues, as well as of the laparoscopic tools, and the haptic interface provides force feedback when the virtual probe encounters the virtual soft tissue, and torques when the virtual forceps or retractors interact with the tissue in more complex maneuvers. Interfaces between virtual tissues having different material properties, for example at organ boundaries, produce tactile cues that the trainee can use to assess the precise location of the laparoscopic tool.

Realistic tactile feedback from tool/tissue interactions relies upon sophisticated computer models of layered, nonhomogeneous tissue that provide real-time dynamic variations on force feedback at tissue boundaries. These calculations are computer intensive, involving such tissue parameters as viscoelasticity, anisotropy, and nonlinearity, and the two principal approaches to developing force-reflecting organ models are particle-based methods and finite-element methods (FEM).

In particle-based models, an organ's particles – or nodes – are connected to each other as if by springs and dampers, each with its own position, velocity, and acceleration characteristics, and each moving under the influence of the implied forces of the surgical tools. In finite-element modeling, the geometric model of an organ is divided into surface or volumetric elements, and the properties of each element are calculated. Finally, all of the finite elements are assembled into a working model to compute the deformation of the organ under the applied forces.

Finite-element methods, although computationally more intensive than particle-based methods, relying as they do on modeling the behavior of compliant biological tissues by differential equations, provide more realistic tissue dynamics.

3.1 Surgical Training

Training is a field in which VR has made and continues to make major contributions. Because the technology lends itself quite well to training scenarios, and provides the versatility that is difficult to duplicate in most medical settings, VR is rapidly becoming the technology of choice in training surgeons, particularly in minimally invasive procedures that are largely conducted by feel. Virtual reality provides the surgical planner or trainee with a safe, veridical representation of patient anatomy – including unusual anatomical anomalies – and instrument dynamics, wherein surgical skills can be acquired or honed.

3.2 Issues and Trends

Surgical training is a nebulous term that means different things to different training institutions, and even to different professionals within a given institution. Thus, in this domain of complex skills and subject matter experts, there are few standards that can be invoked to determine just when a surgical trainee has completed his training. Although subject matter experts may verbalize on such matters as surgical strategies, principal skills, critical procedures, and commonly occurring errors, much of what the trainee is to accomplish can be thought of as spatial and perceptual-motor skills, which are difficult to verbalize. As an example, dissection, which is a fundamental perceptual-motor skill, can be impacted by the trainee’s spatial-orientation skills in exposing the tissue, Thus, the skills underlying surgical performance are not well documented, which leaves a training void that virtual reality may be able to fill.

3.2.1 Spatial Skills

Spatial skills are fundamental to good surgical procedure, and these are amenable to training with virtual reality systems. With practice on a laparoscopic simulator, for example, the trainee can learn to orient the instruments and the tissue to gain proper exposure. It is not uncommon for even trained surgeons to find a procedure easier to implement after an expert has adjusted the camera and instruments. Prior to the adjustments, however, it may have been difficult for the surgeon to verbalize or even recognize the need for an adjustment. These essential spatial skills can be easily trained with virtual reality simulators.

Adequate spatial skills translate into acceptable exposure skills. Tissue exposure is largely dependent upon the surgeon's ability to recognize, store, and access information about the spatial and inertia properties of tissues in the surgical field, and the connections to other tissues. Laparoscopic surgery, because of the reduction in tactile feedback and limited visual field, offers greater challenges to the surgeon's ability to adequately expose tissue. Within the limits of the trainee's spatial abilities, virtual reality can improve tissue exposure by providing a greater sense of the spatial parameters of the surgical field.

3.2.2 Perceptual-Motor Skills

As with spatial skills, the means by which surgeons acquire the requisite perceptual-motor skills for minimally invasive surgery is poorly understood. Here, virtual reality, because of its ability to provide consistent imagery and to vary one or a limited number of variables at a time, can provide answers to that puzzling question. VR may also prove useful in elucidating how perceptual-motor skills are integrated with other cognitive abilities. Unfortunately, until both the visual and haptic aspects of virtual reality systems become capable of rendering subtleties like changes in tissue consistency and opacity, virtual reality simulations will not entirely supplant practice on real patients. Where virtual reality excels is in allowing trainees to acquire spatial and perceptual-motor skills at minimal risk to patients.

3.2.3 Critical Procedures

Simulators that attempt to mimic the entire operation frequently fail because of lack of fidelity in some of the component tasks. However, in any operation, there are critical procedures that must be mastered by the trainee. A critical procedure may be one that if performed incorrectly will result in complications that can impair the outcome of the operation or perhaps endanger the patient. The critical nature of a procedure may not be apparent in every case, but become critical in the face of unusual anatomical formations or uncommon manifestations of a condition. Here, virtual reality can significantly lessen the probability of morbidity by exposing the trainee to the potentially critical procedure in a safe and structured environment. Just as pilots train for emergency conditions on simulators, so surgeons can train for the unanticipated complication and prepare for it.

3.2.4 Spatial Cognition

There are few data that relate the solution of complex problems to integration of spatial cognition. Surgical training is an area where that integration is essential to the development of adequate surgical procedure skills. Virtual reality systems can present trainees with situations in which problem-solving spatial-orientation skills are evoked, and can assess the degree of integration through further problem solving in other synthetic environments. To perform adequately, the surgeon must incorporate a multi-dimensional cognitive map of the surgical field and surrounding or related structures.

Very often, the surgeon’s cognitive maps must be synthesized from multiple 2D images derived from a variety of radiological technologies, e.g. X-ray, CT , MRI, that may not image anatomical structures as coextensive, requiring the surgeon to cognitively determine tissue boundaries, for example. To further complicate the generation of a cognitive map of the surgical field, the surgeon may be presented with functional maps, e.g. PET, SPECT, fMRI that must be integrated with the structural maps provides by the other radiological imaging technologies.

Minimally invasive surgery places an even greater burden on the surgeon, as he must synthesize and update cognitive maps of the surgical field from remotely accessed sensory input, as through laparoscopic instruments whose fulcrums the surgeon must take into account and via video images of the surgical field that can be reoriented. While primarily a training tool, laparoscopic simulators can be used to study how users develop the required cognitive maps of the surgical field. Virtual reality systems can vary the visual and tactile feedback the trainee receives, and the cognitive mapping of the spatial field can be assessed through performance profiles.

3.2.5 Representative Tasks

Minimally invasive surgery is in an intensive development phase of its life cycle. New instruments are being created very day to attack new problems, to enable new procedures, and to ease the training burden. Virtual reality systems are uniquely positioned as a test bed of new instruments/procedures that can provide immediate feedback on the effectiveness, limitations, and problems of introducing new instruments or implementing new procedures. Examples of possible benefits are easy to describe; new instruments, perhaps with a different angle or an additional degree of freedom of movement, can be used in the laparoscopic simulation and immediately compared to the standard instrument; a new laparoscopic procedure is practiced on the simulator only to find that the instruments interfere with each other, whereas in the old procedure, there was room for both of them. Given the power of virtual reality to create and modify minimally invasive surgical procedures, it makes no sense to practice new procedures or test new instruments on patients.

3.3 Clinical Procedures

Although virtual reality is capable of simulating open surgical procedures, it is used primarily as a training device in minimally invasive surgery (MIS), the reason being that other technologies do not provide the sensory involvement necessary for learning closed procedures. Thus, VR has become an invaluable training aid in procedures that require action at a distance, such as exploring the interior of a joint, vessel, or the gastrointestinal tract. Some endoscopic procedures are simply diagnostic, and here, VR systems are utilized in training the use of appropriate diagnostic instruments. VR-based diagnostic-instrument training includes such procedures as bronchoscopy, gastroscopy, arthroscopy, and hysteroscopy.

Virtual reality is also an important training tool for developing interventional skills, particularly laparoscopic skills. VR-based laparoscopic trainers are available for developing and enhancing surgical skills in procedures such as the very common cholecystectomy, oophorectomy (ovariectomy), tubal ligation, endometriosis treatment, and Nissen fundoplication. Endovascular procedures, such as stenting and PTCA can also be trained with VR-based simulation systems. VR systems are also available for training procedures that are commonly used in trauma, such as cricothyroidotomy, pericardiocentesis, chest tube insertion, open and cathetierized diagnostic peritoneal lavage, and IV cutdown.

Even some relatively simple procedures have been found to benefit from training with virtual-reality simulators. For example, catheter insertion and phlebotomy skills can be trained and honed with VR-based simulators.

3.4 Enabling Technologies

The perceptual-motor skills necessary for good surgical practice require both visual and tactile display systems. Also, to provide the necessary feedback from virtual instruments and to assure registration of real and virtual components of the simulation, the system needs to incorporate a tracking device. The tracker will communicate its location – and perhaps orientation – to the computer that is generating the simulation, and these data will be used to update the sensory systems – both visual and haptic – appropriately.

The visual interface may be a video screen, a computer monitor, or one of a variety of HMDs, depending upon the visual requirements of the task being trained. Haptic feedback will most likely be imparted to the trainee through the instrument being guided within the virtual patient. The tracking system will detect collisions between the instrument and virtual tissues, and the haptic system will provide resistance according to the tissue model programmed into the simulation. These three components, working in conjunction, are capable of producing a compelling impression that the trainee is interacting with real tissue.

3.5 Product Descriptions

Companies offering and/or developing products in surgical training are shown in Exhibit 3-1.

Exhibit 3-1: Companies with Surgical Training Products

COMPANY	PRODUCT	FEATURES
Fifth Dimension Technologies (5DT)	Bronchoscope Training Simulator	This virtual-patient system allows the trainee to perfect bronchoscope navigational and procedural skills, using a computer-graphics model of the lungs and a force-feedback system. The trainer uses an instrumented bronchoscope that is inserted into the physical model and whose tip is tracked in real time with 6 degrees of freedom (6 DOF). The 6 DOF tracking data are used to render image that the trainee see with a real bronchoscope in an actual patient. The system is also useful for training therapeutic skills, such as biopsies.
Fifth Dimension Technologies (5DT)	Gastroscope Training Simulator	Similar to the Bronchoscope Training Simulator described above, this system uses the same technology to train gastroscopy. Biopsy skills and difficult procedures like Endoscopic Retrograde Cholangiopancreatography (ERCP) can also be simulated.
Cine-Med	Virtual Clinic (may not currently be available)	This system uses a computer-generated human anatomical model and sensory feedback to simulate endoscopic procedures.
Gaumard Scientific Company, Inc	HAL	HAL is a training reality system that uses Virtual Instruments that mimic the look, feel, and function of real instruments to train ER physicians in ALS skill.
HT Medical		This company has developed robotic tactile-feedback devices for simulating endoscopic and endovascular procedures
Immersion	CathSim	CathSim incorporates the AccuTouch tactile feedback device to assist nursing and phlebotomy students in learning how to start an IV and to draw blood. The system allows the student to see and feel needle and catheter insertion into the skin and vein lumen. By providing a variety of real life patient types and complications, CathSim provides representative scenarios that the student is likely to encounter.

Exhibit 3-1: Companies with Surgical Traning Products (Continued)

COMPANY	PRODUCT	FEATURES
Immersion	Endoscopy AccuTouch® Simulator	This system simulates flexible bronchoscopy, and upper and lower gastrointestinal flexible endoscopy. Using actual patient data and real-time computer graphics to generate anatomic models, and a force-feedback robotic interface device to provide the actual feel of a procedure, this simulator enables students to develop the cognitive and motor skills essential to endoscopy.
Immersion	Endovascular AccuTouch® Simulator	Endovascular procedures, such as PTCA, stenting, and cardiac pacing can be trained through the use fluoroscopic images and a tactile-feedback system designed to provide the subtle feel transmitted through guide wires, catheters and other interventional devices. This system enables clinicians to develop skills prior to performing endovascular procedures on a patient, and to maintain skill levels once acquired.
Immersion	Hysteroscopy AccuTouch® System	This simulation system for training hysteroscopy procedures uses a tactile-feedback system to provide the appropriate resistance as the trainee navigates instruments It can simulate real-life procedures, complications, and tool/tissue interactions that enable the trainee to develop and maintain hysteroscopy skills in a safe environment.
Mentice Medical Simulation	Procedicus MIST	This system provides a graded series of training exercises designed to develop surgical technique employed in such procedures as laparoscopic cholecystectomy. The use of left and right hand training exercises encourage ambidexterity. The system measures performance by time to task completion, number of errors, and overall exercise efficiency.
Mentice Medical Simulation	Procedicus VIST	This vascular-intervention trainer simulates the physics and physiology of the human cardiovascular system for training endovasculat procedures, such as cardiac catheterization, stenting, and pacemaker lead placement trough the use of haptic and visual, e.g. simulated X-ray, interfaces. System modules simulate hemodynamics, blood flow, and contrast-medium mixing; as well as catheter-vasculature interaction..

Exhibit 3-1: Companies with Surgical Traning Products (Continued)

COMPANY	PRODUCT	FEATURES
Mentice Medical Simulation	Procedicus VA	This virtual arthroscopy simulator consists of a basic haptic/visual platform and add-on modules for synthesizing arthroscopic procedures in the shoulder and knee.
Mentice Medical Simulation	Procedicus KSA¯	The Key Surgical Activities simulator provides a suite of training skills pertinent to laparoscopic surgery, including triangulation, scope navigation, cutting, suturing, needle passing, and diathermy.
Next Dimension Imaging	Anatomy Analyzer 2	Anatomy Analyzer 2 is a Windows XP application for creating anatomical 3D models.
Select IT Vest Systems AG	Virtual Endoscopical Surgery Training (VEST)	This endoscopic training system provides a virtual representation of the "standard" human body and anticipated pathologies. Visual and tactile feedback is used to train professionals in endoscopic procedures.
Select IT Vest Systems AG	VSOne Cho and VSOne Gyn	VSOne Cho is a dedicated VR trainer for developing surgical skills required in performing laparoscopic cholecystectomy.VSOne Gyn is used in training for laparoscopic surgery in gynecology.
Simbionix	LAP Mentor	The LAP Mentor™ simulator provides “hands-on” laparoscopy practice for developing basic laparoscopic skills and for practicing complete laparoscopic surgery procedures.
Simulab Corporation	TraumaMan	TraumaMan is a VR system for use in the company’s Advanced Trauma Life Support Surgical Skills Practicum to simulate cricothyroidotomy, pericardiocentesis, chest tube insertion, open and cathetierized diagnostic peritoneal lavage, and IV cutdown; and includes simulated blood flow to operative sites and realistic airflow reactions to procedures.
Simulab Corporation	SimuVision	This simulated laparoscope system uses a boom-mounted digital camera that allows the viewer to change the perspective of the operative site or task.
Simulab Corporation	LapTrainer	LapTrainer incorporates SimuVision into a portable laparoscopic trainer that includes laparoscopic instruments and graphics generated by a boom-mounted digital camera that allows the user to reorient the view within the operative cavity and to zoom in on the operative site.

Exhibit 3-1: Companies with Surgical Traning Products (Continued)

COMPANY	PRODUCT	FEATURES
Surgical Science AB	LapSim System	This trainer utilizes interactive live video to provide a realistic simulation of the operative cavity environment with variable graphic complexity
Surgical Science AB	LapSim Dissection	This advanced LapSim System offers a software expansion to accurately simulate critical procedures of laparoscopic cholecystectomy, such as dissection, clipping, and cutting of the bile ducts and blood vessels.
Surgical Science AB	LapSim Gyn	Lap Sim Gyn provides simulation for the training of tubal occlusion, ectopic pregnancy removal, and the final suturing in the myomectomy procedure.
Verefi Technologies	EndoTower	The EndoTower creates a virtual environment to train surgical navigation skills using an angled laparoscopic lens/camera combination, which skills are important in performing minimally invasive surgical procedures in general and thoracic surgery, orthopedics, urology, and gynecology.
Verefi Technologies	RapidFire	RapidFire is a VR trainer for basic motor skills for laparoscopic surgery, including the laparoscopic fulcrum effect, developing an appreciation of the 3D surgical field from 2D imagery, bimanual target acquisition, and object transfer.
Verefi Technologies	SmartTutor	SmartTutor continually measures the performance of student using the Rapid Fire System, and modifies the training session in real time to either accommodate or challenge the student, thereby providing a zone of optimal learning.
Virtalis (formerly Virtual Presence Ltd.)	Minimally Invasive Surgery Trainer (MISTVR)	This system consists of a frame-mounted pair of trocars linked to a high-end PC, which provides basic perceptual-motor skills for minimally invasive surgery while recording skill level. MISTVR provides basic visual cues and manipulative features for training tissue dissection, arterial/duct clipping, object acquisition, bimanual operation, and object interchange between instruments.

Notes: 3D = Three dimensional; DOF = Degrees of freedom; ERCP = Endoscopic Retrograde Cholangiopancreatography; ER = Emergency Room; ALS = Avanced Life Support; IV = Intravenous; PCTA = Percutaneous Transluminal Coronary Angioplasty

Source: MedMarket Diligence, LLC

3.6 Surgical Training - Market Analysis

There were nine companies with significant sales of virtual reality simulator systems in 2004 and 2005. The total U.S. market for surgical training systems sold in 2004 was approximately $9.9 million. The estimated total U.S. sales for 2005 are $11.6 million and worldwide sales are approximately double U.S. sales. Strong increases in market adoption over the forecast period are expected to result in total revenue for surgical training simulators of more than $26 million in 2009.

Because of the growing acceptance of the value of simulators for training, and because of regulatory requirements promoting use of these systems over use of animals for training, this market is projected to grow initialy at a minimum of 17% annually. This growth rate will increase steadily in later years as training on surgical simulators becomes required as part of medical credentialing. The annual growth rate for simulators is expected to reach more than 25% per year by 2009. The compound annual growth rate over the forecast period is projected at 21.4%.

It is expected that by 2008 the cost of providing surgical training using simulators will be low enough due to decreased equipment costs that there will no longer be a capital equipment price barrier for their acquisition by medical centers and teaching hospitals. This will increase the volume of units sold, and total revenue will grow, despite the decreased average sales price. It is expected that system providers will generate at least 15% of annual revenue by providing updates to software, training, and system support. Another factor driving sales in later years will be the increased use of surgical simulation systems to “warm-up” a surgeon prior to performing a surgery. Already several medical centers are providing video game systems with dynamic interactive environments to surgeons as a way to gain proficiency in complex movements and to sharpen dexterous skills prior to surgery.