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Image Guided Surgery

Introduction

Recent advances in image guided surgery (IGS) are changing the manner in which surgeons are able to execute difficult procedures, most specifically the minimal invasive ones. By building detailed, patient-specific models of anatomy, and augmenting those models with other pertinent information, such as functional properties, the surgeon can better plan the procedure to optimally extract target abnormal tissue while avoiding nearby critical structures. By registering these models with the actual patient position in the operating theatre, one can provide the surgeon with augmented reality visualisations, in which hidden tissue is displayed in exact alignment with a live view of the patient. By tracking surgical instruments relative to the patient and the registered model, real-time feedback is provided about the position of the instrument and its relationship to nearby tissue. Throughout its evolution, the computer has played a major role in IGS. Not only is the computer indispensable in displaying and manipulating medical images, it is ubiquitous in this branch of biomedical engineering, controlling the imaging equipment, reconstructing the images from raw data, tracking instruments, modelling tissue, evaluating surgical performance, controlling robots and facilitating the human-machine interface.

Why Image Guided Surgery?

Because of the precision that image-guided surgery technology provides, surgeons are able to create an exact, detailed plan for the surgery — where the best spot is to make the incision, the optimal path to the targeted area, and what critical structures must be avoided. The technology allows surgeons to view the human body — a dynamic, three-dimensional structure itself — in real-time 3D. The technology creates images that allow surgeons to see the abnormality, such as a brain tumour, and distinguish it from surrounding healthy tissue. It also enables them to manipulate the 3D view in real-time during surgery. The constant flow of information helps surgeons make minute adjustments to ensure they are treating the exact areas they need to treat.

The technology aids in shortening operating times, decreasing the size of the patient's incision, reducing the procedure's invasiveness — all of which can lead to better patient outcomes and faster recoveries. Image-guided surgery also provides new alternatives for patients with multiple medical problems, patients who may not be able to tolerate large, invasive surgeries, and patients whose conditions in the past would have been considered inoperable.

Market Overview

IGS systems combine various high-end technologies, such as navigation technologies, image acquisition and image processing in order to allow 3D visualisation of the human anatomy and the localisation of surgical instruments during minimally invasive surgeries. By synchronising preoperative images with real-time information during surgery, IGS systems provide surgeons with the precise location of objects within the body without actually seeing it with the naked eye. The systems normally consist of an image-processing work station and a tracking system. The imaging approaches used include optical techniques, such as computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy and ultrasound, while the tracking technologies normally in use are optical localisers and electromagnetic navigators. Optical localisers track infra-red rays emitted by light-emitting diodes (LEDs) located on the surgical instruments. Reflectors that are attached to the instruments reflect images to a camera, which is connected to the computer that analyses the images and tracks the LED as the surgeon moves.

The total revenues for the image-guided surgery market in western Europe was 214.6 million dollars in 2010. The market is expected to reach 285.0 million dollars in 2014, growing at a compound annual growth rate (CAGR) of 10.1 percent from 2008 to 2014. The revenues included in this research service are those generated from the sales of new systems. The market growth is mainly driven by the benefits for patients and healthcare providers offered by image-guided surgery, which enhance market acceptance. In addition, as more and more clinical evidence are available and surgeons gain additional experience with these systems, the adoption of image-guided surgery increases. This explains the increasing market growth in recent years. However, the growth is expected to become gradually slower in the following years because the image-guided surgery market in western Europe is becoming mature and is likely to experience saturation, especially in the field of neurosurgery, which is currently a major market segment.

Competitive Landscape

The leader of the IGS market in western Europe was BrainLAB AG, with an estimated 32.7 percent of the market in 2008. BrainLAB AG was followed by Medtronic Navigation Systems with 22.1 percent of the market. B Braun Melsungen and Stryker also occupied considerable amount of the market with 11.1 percent and 7.3 percent market share, respectively. BrainLAB AG enjoys very strong brand recognition in all clinical applications, partly due to the fact that historically the company was the first to offer image-guided surgical systems. As Medtronic, Inc. has a strong brand name in the medical device industry in general, Medtronic Navigation enjoys recognition in the IGS market. Although the company's market share in the orthopaedics segment has decreased during the last couple of years, it is an important competitor in the neurosurgical and the ENT market segments. B Braun Melsungen, Stryker and Amplitude SA are strong competitors in the orthopaedics market segment.

Applications Trends

Orthopaedics

Image-guided orthopaedic surgeries include knee and hip replacements, which are the primary applications for orthopedics IGS and additional applications, such as trauma and emergency interventions and ligament reconstruction. IGS for orthopaedic applications is well accepted in western Europe with the highest penetration rates in Germany, which is the major market for image-guided orthopaedic surgery systems. The amount of orthopaedic procedures done with IGS systems in Europe is constantly growing as market participants improve technologies and increase the value for patients, surgeons and hospitals. Although there is still a need for long-term clinical data in this field, surgeons are willing to perform image-guided orthopaedic surgeries, which reduce the chances for errors and complications in complex and simple procedures. Being the latest clinical segment within the IGS market, the IGS systems market for orthopaedic surgery was expected to grow significantly. In terms of product adoption and usage, the market indeed grew. However, most participants in this market segment do not charge their clients for the system, or charge for part of the cost, gaining their revenues from disposables. Therefore, in terms of revenues from sales of systems, the market has grown more moderately than expected. Nonetheless, the potential of the total orthopedic IGS market is relatively high as this market segment is still young and the usage of these systems is increasing.

Neurology and Neurosurgery

Historically, IGS systems were first introduced for use in neurosurgeries. During the years, these image-guided procedures that involve preoperative images and planning and intraoperative navigation became the standard of care for many neurosurgical procedures. Among the different IGS applications, cranial applications have gained the highest market penetration. Currently, the vast majority of neurosurgeons in western Europe use these systems. IGS systems provide neurosurgeons with the ability to increase surgery accuracy, reducing the high risks associated with neurosurgery, such as damaging healthy tissues and therefore, gained their credibility and are well accepted in the market. Although the current penetration of IGS for spinal applications is much lower, it is believed that the technological advancements allowing 3D imaging, faster registration and enhanced safety will instigate utilisation and support the growth of this market segment. Although already having a high penetration rate, the total neurosurgical IGS market is expected to keep growing as a result of introduction of new products, increasing prices, growing adoption of IGS for spinal applications and high replacement rates.

Ear, Nose and Throat

As ENT surgeries require navigating in small anatomical structures and cavities with limited visualisation, using image guidance in procedures like sinus surgery, cyst or polyp removal, reconstructive, ENT surgery, optic decompression and skullbase surgeries adds a significant value to them. Providing a 3D image of the patient's inner anatomy, IGS systems allow a much better visualisation than common 2D endoscopic procedures. By being less invasive and more precise than traditional ENT surgery, IGS improves outcomes and increase patients benefits by reducing the risk and allowing a shorter recovery time. As IGS systems for ENT applications become simpler and easier for use, more clinicians and hospitals understand its value and use these technologies. Although the acceptance of IGS among ENT surgeons is quite high, the total market for ENT surgeries is very limited compared to other market segments, such as neurosurgery or orthopaedics.

Emerging Applications of IGS

Sentinel Lymph Node Mapping

The first steps for translation of this technique to the clinic have been made in sentinel lymph node mapping. The sentinel lymph node is the first lymph node to which the lymphatic fluid coming from the tumour drains and in which tumour cells will first metastasise. Currently, lymphatic imaging is performed using dye-injection, nuclear imaging, CT, and MRI, which each has their specific limitations regarding sensitivity, resolution, exposure to radioactivity, or practical use. NIR fluorescence imaging allows for high spatial and temporal resolution without ionising radiation, making it an easy-to-use and safe technique. With parallel imaging of visible and near-infrared light, the contrast agents can be traced to the sentinel lymph nodes in real-time, without affecting the visual appearance of the surgical field. Considering the recent clinical results using intraoperative NIR fluorescence cameras or portable NIR-imaging devices, sentinel lymph node mapping is one of the most promising clinical applications for NIR fluorescence imaging in the field of oncology.

Optical IGS

Intra-operative optical imaging camera systems are being developed resulting in the detection of a variety of tumours in mice during surgical procedures. In addition to intraoperative tumour detection, endoscopic systems are under development for diagnostic and surgical applications. In neurosurgery, the use of 5-aminolevulinic acid for detection of malignant gliomas by optical imaging techniques has been recently studied. The intra-operative use for fluorescence guidance has been described in a phase II trial as an effective adjunct in the surgery of recurrent malignant gliomas.

Technology Trends

Regulus Navigator

The Regulus Navigator has been shown to be an accurate, reliable and easy-to-use image-guided device during its clinical trials for any intra/extracranial procedure. The system has also been shown to be a cost effective alternative to significantly higher priced commercial image-guided systems. Technological advancements have revolutionised many areas of medicine. Image guided instrumentation promises to play a substantial role in these advancements for years to come. As we have mentioned, there are many technologies currently being used, or investigated for image guided surgery. Many of these will continue to be refined adding new applications for use such as in breast biopsies, cardiovascular surgery, increased use in Orthopaedics, ENT/Otolaryngology and many more areas of medicine. As the technology advances, so will the list of surgical instruments which can be attached to the image guided device, again allowing for further applications. The goal of developers is to interface virtually any and all instruments the surgeon may wish to use providing real-time visualization of the instrument tip in the actual surgical field.

Display Technology

The essence of an image-guided surgical system is its tracking device. However, an equally important component is the display; it must be capable of displaying the image in three-dimensions, either by presenting the observer with orthogonal planes that follow position of the tracked probe, or else display a representation of the probe within a three dimensional rendition of the patient image. To be an effective tool in the operating room (OR), it must be truly interactive.

Multi-Planar Image Display

Multi-planar image representation is as old as tomographic image acquisition, and even when the resolution of early systems was far from isotropic, vertical slices through the data were demonstrated to be useful in navigating through the images in three dimensions.

Three-Dimensional Displays

The traditional means of displaying medical images was an xray film on a view-box, and even with the advent of 3D imaging techniques like CT and MRI, until recently images were still viewed slice-by slice, either as films on a standard light-box, or on a computer display.

Stereoscopic Displays

Stereoscopic imaging is no longer in general use in diagnostic radiology, although there are some centres that still employ it routinely, while others use it on a sporadic basis. However, since the advent of three dimensional imaging modalities, there is an increased need to navigate through large data spaces quickly.

Head-Mounted Displays

One of the greatest advantages of this approach is that it keeps the images that would normally be displayed on an inconveniently placed computer monitor, within the surgeon's field-of-view at all times. With this system, images from the preoperative studies are always in view. In addition, the real-time, video-based endoscopic images, being used for navigation within the ventricles for example, are always available to the surgeon without the need to turn away from the site of the operation.

Conclusion

Despite its current challenges with regard to setting up an apt OR infrastructure, image guided surgery is having a powerful influence on medicine today. With the computer as a valuable assistant to the physician, surgeries of the future are likely to be less invasive, shorter, less risky and more successful.

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