How GE Research Developed MRI (Magnetic Resonance Imaging) Guided Surgery
By Kirby Vosburgh

GE Corporate Research and Development (CRD) and GE Medical Systems (GEMS) have collaborated since the 1970s on a series of novel developments in the CT (Computed tomography), MR and ultrasound imaging fields. This relationship and joint projects with research hospitals around the world have supported GE's global leadership of medical imaging scanner sales.

The MR-guided Therapy (MRT) system concept was created when Morry Blumenfeld of GEMS was asked to look for the "next big thing" in 1987. Initially, Morry's team made mock-ups of several potential designs, using combinations of existing CT, MR and ultrasound systems. Physicians were asked to evaluate these concepts in simulated clinical settings, including orthopedics, interventional suites, emergency rooms and operating rooms. Morry realized that surgeons and other interventionists would benefit from real-time MRI. This would let physicians see diseased tissue and important structures such as blood vessels directly, and provide immediate access to the patient

Dr. Ferenc Jolesz, the director of MR Imaging at Brigham and Women's Hospital (BWH), had a strong relationship with GE in the late 1980s. He also had recognized the potential of 3D digital imaging, and hired Dr. Ron Kikinis in 1998. Dr. Kikinis worked with CRD experts Harvey Cline and Bill Lorensen on advanced image processing and real time displays. In 1990, Dr. Kikinis founded the Surgical Planning Laboratory, which today is a world leader in these fields.

Simultaneously, CRD's Trifon Laskaris and his colleagues were developing a novel magnet for a government agency which he described as "a pair of hula hoops." An advanced superconducting material was used which would not would not require liquid helium cooling during normal operation. This simplified the overall design, and permitted new magnet configurations

Morry thought this was exciting, especially the idea that we could build the whole magnet with two hula hoops! The superconducting coils would then surround the patient, leaving a gap with a stable high magnetic field between the coils where the patient could be positioned.

Magnetic gradient structures and radiofrequency (RF) coils are also necessary to create MR images. Special designs with a large gap to permit access to the patient were developed to image in all three principal directions. RF signals were transmitted and received with the use of either a modified birdcage coil or surface coils. These surface coils could be integrated within a sterilized surgical drape and placed directly on the skin of the patient, thus providing high resolution images. Commercially available RF coils were also satisfactory for many applications. A 3D digital system was integrated into the system to permit the clinician to position the image plane directly from within the imager.

The team then designed a functional prototype, although the hula hoop profile grew to look more like a donut. Lead CRD personnel were Trifon Laskaris (magnets), Peter Roemer (system components and software) and John Schenck (clinical interfaces). Kirby Vosburgh was the project manager. The team worked closely with Robert Newman and a group of engineers and designers at GEMS.

Leaders of the MRT Prototype Design and Development. Peter Roemer, CRD, Kirby Vosburgh, CRD, S. Morry Blumenfeld, GEMS, E. Trifon Laskaris, CRD, Robert Newman, GEMS

While the magnet and imaging coils required cutting edge technology, the imaging console and electronics of a GE product MRI were only modified, and a new patient table was added. This approach limited the complexity of manufacturing. Dr. Jolesz organized discussions with neurosurgeons, otolaryngologists, gastroenterologists, and general surgeons to confirm the value of the MRT concept and refine design details.

The prototype system built at CRD began running in the fall of 1993. As Rob Newman noted, “The development of MR-compatible instrumentation and new ways of using intraoperative imaging changed the way radiologists, surgeons, and oncologists worked. None of would have dared to predict that this first prototype unit would keep on chugging for almost 13 years.”

A series of submissions to the FDA were made by GE to support clinical trials of key concepts:

- Imaging the loaded spine,
- Demonstrating the utility of real time image plane selection, to permit images of moving anatomy like the shoulder or elbow,
- Integrating the tracker into MR-compatible instruments such as a biopsy gun to direct the scan plane in real time and guide interventional procedures.

Figure 2. The positioning of the patient in the MRT System. Physicians can stand on both sides of the patient with their hands directly in the imaging volume.

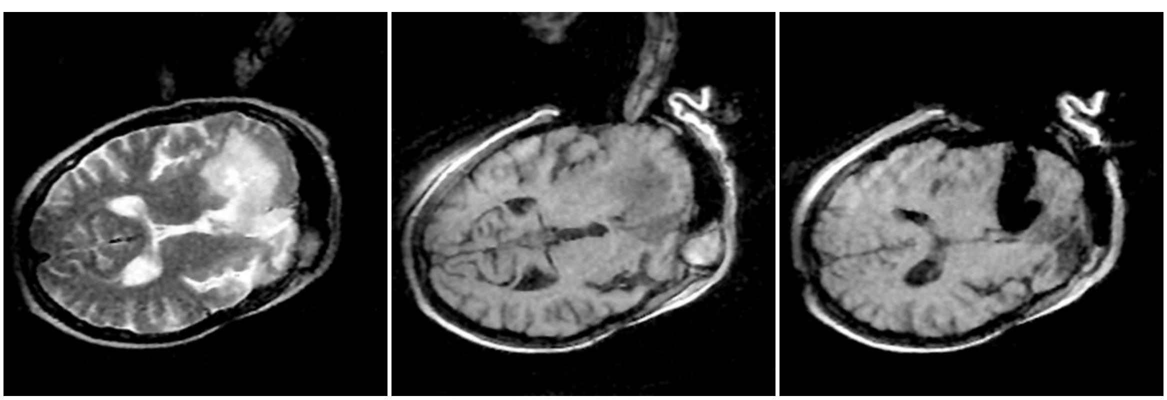
The next step was clinical evaluation. The prototype MRT system was installed in March, 1994 in a specially constructed, magnetically shielded hospital suite at BWH. This set of rooms provided the features of MR imaging and interventional radiology as well as those of a conventional operating room. The physician could perform various interventional, endoscopic, or open surgical procedures while standing or sitting and easily viewing real time patient images. The patient could be positioned in many ways. This provided several diagnostic imaging and procedural options.

The MRT prototype system installed at BWH. Depending on the procedure, the patient table may be positioned coaxially or perpendicularly to the axis of the scanner. MR-compatible anesthesia equipment and MR-compatible instruments can be placed nearby. LCD screens to monitor imaging data during a procedure are mounted on both sides of the work area at eye level.

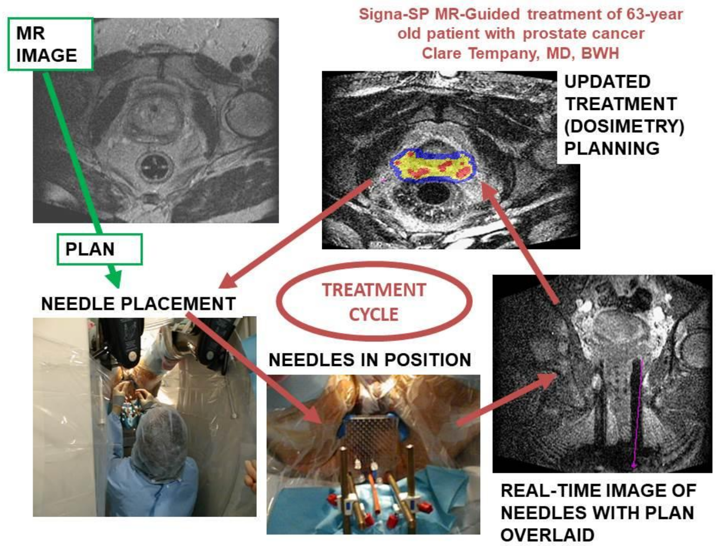
The first tests of the MRT system in human subjects were conducted at BWH in April 1994 by Dr. Stuart Silverman. The image position tracker was integrated into an MR-compatible biopsy gun, and provisions for creating a sterile field added. Dr. Silverman performed image-guided tissue biopsies in the liver and several other sites. Other diagnostic applications included functional studies of muscles and joints and images of the spine in various sitting positions. Soon, general anesthesia was provided by modifying an existing MR-compatible product used for pediatric care. Over time, several vendors were able to supply a variety of MR-compatible ceramic instruments. As these needs were met, Dr. Peter Black and his colleagues began neurosurgical procedures.

A view from the surgeon's position inside the Signa SP magnetic resonance imaging system. In neuro-surgical procedures the patient's head is fixed with an MR-compatible Mayfield clamp. After the appropriate entry point is selected by MR imaging, the skin site is marked. Sterile drapes are placed over the flexible surface coil when the sterile surgical field is being prepared.

They started by treating a patient with a subdural hematoma. They then began a long series of operations which required removal of a portion of the skull (craniotomies). The real time imaging capability of the MRT system was particularly helpful in showing how the brain moved during these operations. Dr. Alexandra Golby, who is now the Director of Image Guided Neurosurgery at BWH, summarized the impact of the advances enabled by the MRT system: "Neurosurgery has become a routine elective procedure with most patients leaving the hospital in a few days, usually in better or an equivalent neurologic condition than they were preoperatively. These astounding advances are due to technical innovation in imaging, visualization, and operative techniques that allow the surgeon to have a much better understanding of the anatomy and pathology that are the targets of the intervention."



Intraoperative image-guidance during craniotomy to access a brain tumor (malignant glioma). *(a)* T2-weighted magnetic resonance (MR) images were acquired within the Signa SP, preoperatively. Localization for the best entry site for craniotomy was accomplished by visualization of the surgeon's finger in the MR images. *(*b) This T1-weighted image was taken after the craniotomy. Localization was accomplished by the surgeon's fingertip on the brain surface before tumor resection. T1-weighted MR images. *(*c) T1-weighted intraoperative MR image shows the resection cavity.



Needle placement for MRI-guided prostate brachytherapy. The patient is in the lithotomy position with a perineal template in place. As shown in the lower left images, there are two needles placed through the template, into the prostate gland. On the lower right, a coronal fast-gradient-echo image shows the two needles in place. The needle on the patient's left side is slightly off target, as shown by the *purple line*. The purple line is based on the preplanned trajectory and position as prescribed by medical physicists. The needle may be repositioned, or the subsequent placements may be adapted, as directed by the updated dosimetry planning.

MRT enabled more "first in human" studies in the diagnosis and treatment of prostate cancer. The key factor was the ability to guide needles accurately through the skin to acquire tissue samples and to place radiotherapy seeds. Dr. Clare Tempany pioneered the MR-guided prostate biopsy approach. With Anthony D'Amico, Robert Cormack, and other collaborators, she then showed that these techniques enabled far more accurate cancer detection and characterization than the established ultrasound-guided procedures. As well, these MRT clinicians showed that patients with aggressive cancer can be treated far more effectively. The ability to observe seed placement as the treatment progresses (first shown in MRT) enables the radiation dose to be optimized so that all of the cancer is treated and the normal tissue spared. The long term impact has been that patients can be treated more effectively, and, today, not treated at all when the disease is growing very slowly. In addition, Dr. Akila Viswanathan built on these results to demonstrate a lifesaving protocol to treat late stage cervical cancer.

Other "first in human" procedures included freezing (cryotherapy) of liver and kidney tumors, and drainage tube placement in the kidney.

Here is a summary of the cases that made up the more than 3000 procedures done in the first MRT system:

- Neurosurgery Cases: 1439 (1026 craniotomies, 336 brain biopsies, 37 pituitary cases, 16 cyst drainage procedures, and 24 brain laser cases)
- Brachytherapy cases: 448
- Cryotherapy cases: 264
- Other multi-patient series included breast cancer biopsies, upright spinal imaging, and pelvic muscle characterization.

This work by the BWH clinicians convinced several other leading medical centers to install production versions of the prototype design, marketed under the name “Signa SP.” Thirteen commercial systems were produced in Milwaukee. They were sited in Quebec Canada, London UK, Oslo Norway, Zurich Switzerland, Kiel Germany, Leipzig Germany, Tel Aviv Israel, Pittsburgh Pennsylvania, Louisville Kentucky, Jackson Mississippi, Stanford California, and Osaka Japan.

One of the shortcomings of the high temperature magnet design was that the superconducting magnet was kept cold with an external refrigeration system. It could only “ride through” a total power outage for a few minutes before the magnet stopped working. Nonetheless, the system was used for clinical care around the world until early 2007. In 2005, the National Institutes of Health (NIH) funded the BWH-based National Center for Image Guided Therapy and the equipment for the Advanced Multimodality Image-Guided Operating room (AMIGO). This suite enabled combining MR-guided procedures with advanced CT, nuclear medicine, and fluoroscopic systems. The MRT clinical and research teams have continued to thrive in this larger and more extensively equipped facility.

Today, over 200 medical centers have installed various specialized systems to provide MR guidance to interventional and surgical procedures, but none of these have the direct real time imaging and access to the patient that the initial GE MRT design provided. Through its technical and clinical impacts, MRT led the world with its breakthrough accomplishments.

Kirby Vosburgh holds degrees from Cornell and Rutgers in applied physics and physics. His PhD thesis still stands as the most precise measurement of the lifetime of the K-long meson. At Princeton, he was a primary contributor to the team that accomplished the first acceleration of heavy ions to relativistic energies. He joined GE Corporate Research in 1972. After participating in several product development projects, he was promoted to be a research manager, with increasing levels of responsibility over 22 years. His laboratories developed successful products for many parts of GE. In 2000, he joined the faculty of the Harvard Medical School. As a Principal Investigator, his teams of physicians and engineers have conducted studies in animal models and human subjects to validate new methods for surgical and endoscopic interventions.