Designing an Efficient and Effective iMRI Facility

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Introduction

Intra-Operative MRI (iMRI) is quickly becoming the go to technology in the ever evolving integration of various radiologic modalities for invasive and non-invasive patient procedures and treatments. Intra-Operative MRI is defined by the use of an MRI magnet during a surgical or treatment procedure. This can be achieved with a moving magnet that is brought into the theatre or by moving the patient to the room containing the magnet. In both cases, imaging is performed prior to, during and after the surgical or treatment procedure. The real time availability of the high resolution MR images is improving patient outcomes in a widening arena including, but not limited to, neurosurgery, cardiovascular and radiation oncology. This article will provide an overview of current iMRI technology and review design, location, safety and performance considerations to ensure an optimally functioning iMRI facility. Following a successful installation, maintenance guidelines are provided to protect your iMRI investment for years to come of optimal imaging and patient care.



An MRI technician can concentrate on viewing images while a smart logic system in place secures the doors and monitors any activity that could compromise the sterility of the surgical Intra-Operative MRI environment. All images courtesy of ETS-Lindgren.

iMRI Overview

iMRI provides surgeons and oncologists precise locations for removal or treatment of diseased tissue while preventing damage to healthy tissue. This is highly critical when operating on the brain and especially when tumors are near key brain function areas. Radiation treatment therapy used in conjunction with MR imaging is minimizing the damaging effects of previous methods by specifically pointing the radiation beam to only the cancerous tissue. It is with these relatively new and developing cross modality technologies that the medical industry is changing the way we approach treatment options.

When a hospital is considering an iMRI suite, defining the types of procedures and the volume that will be supported by the iMRI is the first step. This will provide the basis for the design criteria. From this the type of

MRI machine, the supporting devices and additional modalities, the number of operating room (OR) theatres and the area of building space required as well as the necessary staffing are determined.

An MRI suite is a considerable capital investment so getting maximum use from it is crucial. Planning the suite to use the MRI for standard diagnostic scans around surgery schedules expedites the return on investment (ROI) and maximizes the use of the equipment and valuable real estate. If the suite will have high surgical usage rates that will limit MRI availability for use by the radiology group, this may not be feasible, but this option will increase the value of the investment.

Pre-Planning for Cost-Effective Design and Location of an iMRI Facility

When a hospital is considering an iMRI suite, defining the types of procedures and the volume that will be supported by the iMRI is the first step. This provides the basis for the design criteria. Considerations for cost-effective design are summarized below.

A. Moving or Stationary Magnet System Configurations

MRI can take on multiple configurations starting with either a moveable or stationary magnet system.

A moveable magnet system offers the optimal procedure scenario in that the patient remains stationary throughout the surgery or treatment. This provides the doctor with the assurance that the treatment area remains in the exact location the image indicates and offers the most real time feedback available. This process offers the highest likelihood that the procedure will be successful the first time and not require additional future surgeries. The patient gets the optimal results in treatment outcome and post treatment quality of life.

A stationary magnet system offers better procedural control for safety as the MRI environment is primarily static. The strong magnetic field remains in its own room so is less susceptible to human error that may result in ferrous materials being introduced that could put the patient, staff or equipment in jeopardy. This system requires less Radio Frequency (RF) shielding which reduces overall cost. The potential for poor image quality from possible RF shield degradation is lower since only the magnet room requires RF shielding. These advantages come with key disadvantages in that the patient must be moved to the MRI machine which presents the undesired movement of a surgically open and sterile patient. The possibility that tissue will shift from the time of the image to the restart of the operation or treatment while the patient is moved back to the operating room is another primary concern.

Determining if other modalities will be used in the suite is another major consideration when beginning the design and implementation process. CT, PET CT, Angiography and X-ray among other technologies may be combined to work in conjunction with and in addition to iMRI. Having multiple technologies available in a single theatre is helping medical specialists develop innovative treatment procedures and is opening the realm of future possibilities.

B. Vibration and Electromagnetic Interference Considerations

Designing and installing a moveable magnet system is a more complex endeavor than a stationary MRI, but both present their own challenges. For surgical theatres a primary issue is how to structurally support the weight of an MRI as many OR departments are located above the ground floor. Both structural vibration and electromagnetic interference (EMI) are always concerns when siting an MRI and must be considered when evaluating potential locations.

An EMI and vibration survey should be performed in the proposed location to confirm the space is within the selected magnet specifications. An advance survey is not possible when the project is new construction so the area must be designed to meet these requirements with a post construction survey verifying compliance. When planning an installation in an existing building, there is a greater likelihood that there are existing conditions which may prevent the space from being approved. Elevators and electrical transformers are top EMI contributors while air handling systems, elevators and vehicles in parking garages can cause vibration issues. Whether with new construction or use of existing space, most issues can be resolved through EMI shielding, active cancellation, vibration dampening or relocation of the source. All of these will add to the overall project cost so advanced planning that takes these various items into account upfront will minimize the budget impact later.

A stationary magnet must be supported by a reinforced or thickened building slab which makes the design more complicated on upper floors. Vibration becomes more prevalent in the concrete slab of a building as it gets higher above ground level. Floating slabs or vibration dampening pads are often part of a structural engineer's design to meet the magnet's vibration specifications.

A moving magnet is typically tied directly to the building steel structure. The building steel gets less vibration transferred through it than the concrete slabs, reducing the need for special dampening applications. Additionally, vibration dampening is designed into the hanger supports as part of a moving magnet system. However, the additional structure required to hang the magnet can create other design challenges. Mechanical, electrical and RF shield plans must work around this additional steel structure. The resulting space limitations require very detailed design coordination to provide for the extensive air transfers and electrical support required in an OR. The travel of the magnet also increases the area of concern for EMI and potential effects of the magnet on other equipment in the OR that will need to be taken into account.

Typical architectural plans have one or two OR's connected to the magnet room with direct access via double sliding or double swing RF doors. These RF doors are designed to accommodate the magnet system used whether the patient is moved to the MRI or the magnet is moved through the doors to the patient in the OR. Additional access points are included to provide for the best patient and personnel work flow and safety. Adequate vision panels from control rooms, scrub areas and sub-sterile rooms are also critical to the plan.

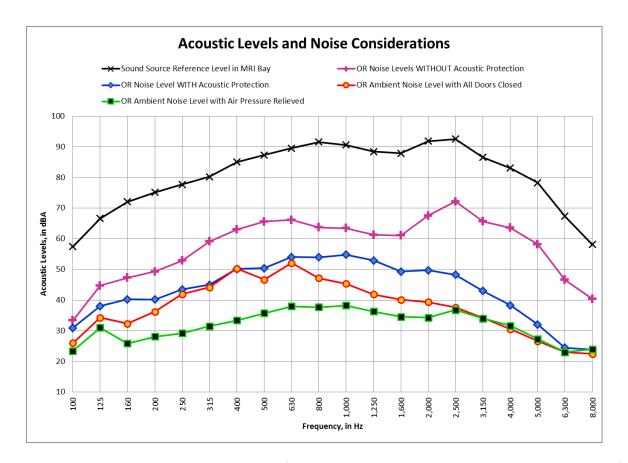
As modalities and devices are added, the planning complexity grows. RF and radiation shielding must be in place per the equipment specifications. Equipment, devices and components cannot be allowed to compromise the performance, work flow or sterility of the suite, but in the same context the work flow may need to be adapted from that of a typical OR to accommodate the unique functionality of RF and radiation shielded doors. Each and every item used in the various rooms must be evaluated for fit, form and function within the varying environments to which it will be exposed. Devices to be used in rooms with the magnet must be MRI compatible and MRI safe or protocols must be in place to move them to an acceptable location so as not to interfere with the imaging or become a projectile in the magnetic field. For radiation treatment rooms, long term exposure to high dose radiation can deteriorate internal electronics and pneumatics that may shorten the working life of certain devices. Plans must be in place to avoid failures through maintenance or replacement in advance of the estimated life span.

When considering all the options, it is highly recommended to bring a collaborative group of experts to the table well in advance to optimize the plan for the space. The architect, structural, electrical and mechanical engineers as well as magnet system, integration system and RF shielding vendors must work closely with the hospital's

surgical, radiology, maintenance and life safety departments to ensure all facets of the final system provide for the optimal procedural flow while maintaining sterility and safety protocols.

C. Acoustic and Magnet Noise Considerations

Acoustic considerations are an important factor in the overall suite design since the MRI magnet can be quite loud during scan sequences. If the magnet bay is also intended to function as a clinical imaging suite when not needed during a surgery, then the OR area needs to be protected from the acoustic noise generated during MRI scans. This allows both areas to be used simultaneously for more efficient use of the hospital resources. While there is a fair amount of ambient noise present in an OR, the sudden and loud noise from an MRI scan could startle people working in the OR, or make the environment uncomfortable and distracting. A small amount of noise may be present from the MRI, but it should be minimized to a level that will not surprise people in an adjacent room.



The graph above shows the various levels of noise present in the OR area based on a certain level of noise in the MRI bay. The black line at the top of the graph is the noise level in the MRI bay using a sound source designed for acoustic testing.

The remaining curves show:

The noise level in the OR with the magnet bay doors closed but with no acoustic treatment;

The same doors with acoustic treatment applied;

The ambient noise level in the OR with all doors closed (high level of wind noise due to the positive pressure in the OR); and

The ambient noise level in the OR with a door slightly open to relieve the wind noise.

The 10-20 dB increased noise without any acoustic treatment can be a distraction to those working in the OR. With acoustic treatment, the noise from the MRI room is reduced to levels very close to the ambient noise level in the OR and greatly reduces the potential distraction created by running a scan sequence on the MRI.

D. Patient and Personnel Safety Considerations

The intra-operative environment is an emerging market with considerations beyond the typical operating room environment. Patient safety is the first and primary concern when designing an intra-operative suite. But there are additional safety concerns that go beyond those of just the patient.

Maintaining a sterile environment is crucial for the patient. Typically, a positive air pressure is maintained in the OR to minimize the possibility of air-borne pathogens entering the area. With the larger doors needed for the

intra-operative environment, and multiple, interactive room configurations, the air handling in these areas may require additional planning to ensure proper air pressure in the OR and adjacent areas. The design of the doors and rooms, and the control of these areas, requires additional design considerations. Since MRIs are now typically used in the intra-operative areas, a shielded enclosure is required for good imaging from the MRI. The design of the doors used in the iMRI area need to have surfaces that may be easily cleaned and minimize dust collection points that require cleaning. The thresholds of the doors need to be free of exposed fasteners and areas that could collect dirt and organic material that pose a sterility issue and can be difficult to clean without compromising future MRI image quality.

Specialty doors, such as those shown at right, maintain the RF shielding integrity of the imaging area, while also ensuring patient and equipment safety with an interlock system, flush threshold, easily cleanable design and push button automatic operation.



Doors used for RF shielding are designed for specific functionality in RF shielding applications, but OR and emergency situations may require additional considerations. The emergency situations can range from personnel needing to get into the OR quickly, bringing a patient out of the OR quickly, securing the OR in the event of a fire, and ensuring the safety of personnel (firefighters) around the magnet during a fire – these are some of the prime examples of these considerations. For these reasons, a detailed conversation with the end users at the iMRI facility is generally required to fully understand the policies and procedures that govern the intended use of the area by the hospital. Because hospitals vary in their policies and procedures, the design of the intra-operative suite needs to allow for flexibility during the design stage.

The large magnet bay doors are generally intended to provide magnet safety for the OR personnel and others in the event of an emergency. In the unlikely event of a fire, for example, it would not be good to have firefighters

rushing into an area where the MRI magnet is present. Also, since intra-operative is a relatively new market, personnel who are used to working in the OR may not have experience working around a high-field MRI magnet. The magnet bay doors provide a safety barrier for protecting people who need to be in the same area as the MRI, but may not have experience working around an MRI magnet.

Specialized control systems are used to provide the safety functionality mentioned above. These same control systems also provide equipment safety to avoid collision problems between moving equipment. If one piece of equipment will be moving through a door, the controls prevent the equipment from hitting the doors, and prevent the doors from closing on the equipment. This prevents damage to the intra-operative equipment, and eliminates unexpected movement that could surprise people working around this equipment.

Since time is critical during surgery, it's important to make sure that imaging scans are not interrupted when in progress. The control systems incorporated into the intra-operative suites help ensure that the imaging environment remains intact during a scan by preventing unauthorized access to the area during these critical times. The configuration and intended use of the intra-operative area will generally define what level of access control is required in the suite. Interlock conditions prevent certain doors from opening during a scan sequence, protecting the imaging environment and ensuring proper RF shielding for MRI imaging, and radiation shielding for angiography and CT imaging. These interlocks are tied closely to the safety measures mentioned previously, to ensure optimal functionality of the imaging equipment combined with patient and personnel safety. Again, a comprehensive discussion with the hospital and end users of the suite will ensure that the entire area functions as expected for the surgical team and safety is maintained.

E. Control and Interlock Considerations

The control systems used within the intra-operative suite are an important consideration during the design phase of the project. Control systems should be flexible to accommodate different user needs and should provide a user-friendly interface for the users of the suite.

In some cases, this will be an HMI (Human-Machine Interface, otherwise known as a touch screen controller) that can display user-friendly information for decision purposes. This includes a graphical display for controlling the opening and closing of a door system, displays for interlock conditions that may prevent certain actions from taking place, displays for when there is an emergency stop condition, and other functionality that the end-user may find useful or necessary. Since there are a number of touch screen controls typically used in an intra-operative suite today, having the information for use and control of the equipment easily understood by the user is critical. The other advantage of a touch screen controller is the ability to present information in other languages with a couple of quick touches on the screen itself.

The controls can also be simplified for more straightforward use if desired. Push plates used to open and close doors can easily be used in place of the touch screen controller. This configuration allows the user to use the back of their hand, their elbow, or, if mounted lower, their knee or foot to open a door.

The control system is very important for controlling the intra-operative environment and the equipment used in the suite. Maintaining a good RF shielded environment whenever the MRI is in use is very important. For this reason, doors in the entire intra-operative suite are typically interlocked to prevent certain doors from being

opened during a scan sequence. These interlocks are dependent on the current configuration of the suite and the state of the MRI (idle or in use).

The control system must also use inputs from other equipment within the suite, and from other systems within the hospital, such as fire alarms and security systems that will be used to define the final operation and use of the suite.

The final configuration of the control system will depend on the equipment being used in the intra-operative suite, the processes and procedures in place at the hospital, the number and types of doors used in the suite, and the safety requirements of hospital.

Other Modalities

Intra-Operative suites are not limited to MRI scanning technology. Other modes of scanning include angiography, CT, and linear accelerators for cancer treatment. With these other modalities, RF shielding may or may not be required depending on the configurations of the suite and whether or not the equipment will be sharing a common space.

However, radiation shielding will be required with these modalities. The amount of shielding required will be dependent on a number of factors, and a specialist in radiation shielding will typically be used to determine the amount of shielding required. These specialists are usually physicists who either work for the hospital or are on retainer, or a third-party consulting firm with the experience and credentials to ensure the safety of those around these areas when they are in use.

The same safety concerns beyond just radiation safety also apply to these modalities as well, ensuring that people can get into and out of the suite as needed during normal use and during emergencies, and ensuring that the equipment present in the suite cannot collide with or otherwise damage other equipment in the suite.

Preventative Maintenance for an iMRI Facility

A key to the continued successful use of an iMRI theatre is the assurance that the equipment and supporting technology are always working at top performance levels. This requires that preventative maintenance (PM) is scheduled and performed on a regular basis. Equipment vendors offer PM and service contracts which provide for a predetermined number of annual visits and varying service response times. The number of visits scheduled depends on the level of performance guarantee the hospital desires and the manufacturer's suggested maintenance schedules.

As with any MRI, periodic maintenance is required to check and fill helium levels, examine cabling for wear and damage, review image quality through internal diagnostic testing and checking coils and patient tables to ensure they are functioning as expected and are in good condition.

The RF shielding system that is integral to obtaining the highest quality images is another important component requiring maintenance. iMRI by design requires a higher level of RF shielding technology to allow for the best operational flow of patients and staff to access the MRI machine when and where it is needed. The RF doors used in the shielding of an iMRI are normally custom sliding doors with auto opening and closing functionality. These are typically pneumatically operated to provide the best RF performance and longevity. These doors

along with ancillary personnel RF doors require frequent cleaning which can be performed by hospital staff. The operational maintenance of these doors should be performed by certified RF shielding technicians to ensure continued RF integrity. All RF contacts, mechanisms and control systems shall be reviewed for wear and tear with parts replaced as needed. A recertification of the entire RF shield should be performed annually through RF testing by a qualified test agency.

In conjunction with equipment and component maintenance, simulation of a full procedure should be made periodically to confirm that everything is working as a system. Interlock conditions between systems, equipment and doors must be verified. Access control, door control and life safety systems shall be tested. Personnel must be up to speed on the processes that are required in the suite.

In an iMRI it is not only the typical periodic maintenance that is required. The scheduling of patient procedures in many cases is not subject to postponement or delay due to equipment failure or something as simple as a door not functioning. It is important that the equipment and shielding suppliers are also under a service contract that provides for emergency response to resolve issues that may otherwise prevent a surgical or scan procedure from taking place as scheduled.

Conclusion

iMRI is leading edge technology in the development of new medical applications. Researchers and surgeons are continually expanding the use of these high quality MR images to provide the best possible vision of tissue in real time to integrate with a growing variety of surgical procedures, treatments and modalities. As hospitals look to the future, including iMRI is a key to offering the best possible patient care and results. Successfully implementing an iMRI suite requires front end planning by experts in the field to ensure all aspects of these complex projects are accounted for. The processes of setting the procedural expectations and goals, designing and constructing the suite, installing equipment, training personnel and post implementation maintenance are all brought together to create a cost-effective, unified and smoothly operating iMRI system that will serve the hospital's and patient's needs long into the future.

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