Final Publishable JRP Summary for HLT06 MRI Safety
Metrology for next-generation safety standards and equipment in MRI

Overview

This research project has contributed to the safer application of magnetic resonance imaging (MRI). A new patient safety concept developed in this project will help manufacturers to speed up innovation cycles and will allow the safe scanning of previously excluded patient groups. In addition, a foundation has been laid to bring a ground-breaking new technology in cancer treatment, MRI guided radiotherapy, to the patient.

Need for the project

The health and safety of European citizens and the effectiveness of medical procedures needs to be improved. Each year, about 23 million EU citizens undergo an MRI scan during which their body is exposed to powerful and potentially hazardous radiofrequency (RF) pulses. Tissue heating is an established health risk for patients and is caused through absorbed (RF) power (measured by the Specific Absorption Rate (SAR) in watts per kilogram). In order to ensure the body is not exposed to unsafe levels the distribution of the RF electromagnetic fields inside the body have to be monitored. The traditional approach to assess MRI safety had limitations and became a barrier for innovation as it is not applicable to emerging MRI technologies such as ultrahigh field strengths (e.g. 7 T) or parallel RF transmitters (pTx) and is not capable of dealing with patients carrying a metallic medical implant. A new safety concept based on numerical simulations to compute the distribution of RF electromagnetic fields inside the human body is in principle well suited to solve both problems. However, additional work needed to be carried out to validate the simulation results, to quantify their uncertainty, and to establish whether the concept can deal with metallic implants and emerging technologies. This would strengthen the market position of the European Medical Technology industry. The European Parliament Directive 2004/40/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from electromagnetic fields has raised concerns that the directive might effectively ban MRI as employees might no longer be allowed to approach an MRI scanner and therefore work needed to be done to quantify these risks to provide advice for EU decision makers and strengthen the citizens' confidence in their decisions. Furthermore, MRI is an ideal candidate to be used in image guided radiotherapy for cancer treatment however it poses the new problem of how to provide reliable and traceable data on exposure levels (photon dosimetry) within the electromagnetically harsh environment of an MRI scanner.

Scientific and technical objectives

The overall aim of the project was to enhance the safety of MRI for patients and staff while simultaneously eliminating *unnecessarily* restrictive exposure limits, thus improving the diagnostic value and efficiency of MRI. By providing a rigid risk assessment for emerging technologies such as ultrahigh magnetic fields, parallel transmission or MRI guided radiotherapy, the project intended to support a faster market introduction of new developments from European manufacturers. The scientific and technological objectives of the project are listed below. 1 and 2 are independent objectives and together both are needed for the JRP to achieve its goals. They are pursued in parallel and the interplay of simulations (objective 2) and validating measurements (objective 1) represents the very core of the project. The other objectives build on these and apply what was developed.

1. to provide traceable measurements of RF electromagnetic fields, and hence the absorbed RF power, generated by MRI scanners and to use these measurements to validate numerical modelling results;
2. to develop a mathematical modelling concept and use it to calculate RF electromagnetic field distributions and related thermal effects inside the human body;

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3. to assess the risk from slowly varying eddy currents inside the human body when a subject moves through the inhomogeneous static stray fields of MRI scanners;
4. to develop a validated measurement method suitable to assess the RF related hazards associated with emerging new MRI technologies such as parallel transmission or ultrahigh magnetic fields;
5. to develop a dosimetry method for emerging new MRI technology MRI guided radiotherapy, comprising a system for traceably measuring the absorbed dose to water for high energy photon beams in an MRI-accelerator combination, and to assess potential changes in relative biological effectiveness of photon beams due to the magnetic field;
6. to develop a concept to assess the risks due to the presence of passive, metallic, medical implants inside the patient's body during an MRI scan.

Results

Objective 1, *"to develop a metrological concept and reference instrumentation to provide a set of traceable measurements of RF electromagnetic fields generated by MRI scanners and to use these measurements to validate numerical modelling results",* was achieved by the following results:

- Reference instrumentation and methods for calibrated measurements of RF electromagnetic (*E*- and *B*-) fields were developed. This allowed the validity of simulation results to be checked with respect to the electromagnetic fields generated by the RF transmit coil of interest. The power associated with these fields is absorbed in the subject body; safety-wise this is the most critical part.
- The most widely used and hence most relevant RF transmit coil in an MRI scanner is the so-called body coil. It is an integral part of the hardware, not easily accessible and only imprecise, 'generic' models of these coils are available from the manufacturers. A detailed and validated coil model is a necessary requirement, however, for any quantitative simulation of the fields generated by this coil. A procedure was thus developed, allowing to test and iteratively refine the computer model of such a coil by comparing modelling predictions and measurements results at each step. The whole procedure was successfully applied to the body coil of a clinical scanner, demonstrating its effectiveness.
- Finally, the developed instrumentation was applied for a few reference measurements on different scanners and for different RF coils and the results were compared to simulations. The agreement was within about 10 % which is fully sufficient for the given purpose, demonstrating the validity of the concept.

Objective 2, "to develop a mathematical modelling concept and use it to calculate RF electromagnetic field distributions and related thermal effects inside the human body", was achieved by the following results:

- An assessment and comparison of different numerical techniques for RF simulations was made using new concepts, developed within the project, as well as commercially available software. Depending on details of the problem, each technique can over or under-estimate the real (measured) field values. Nevertheless it was possible to draw some general conclusions about the suitability of a given method or software package for certain classes of problems.
- To assess the validity of the numerical results, comparisons of computations and measurements were performed under controlled laboratory conditions. Generally, they show good qualitative and satisfactory quantitative agreement. Worst case discrepancies of up to 30 % were found for the RF electromagnetic fields near metallic implants. Within the scope of the present project this is sufficient but ultimately an agreement within 10 % is desirable for all cases.
- When studying thermal effects in tissue only a weak spatial correlation was found between local RF power deposition (the so-called specific absorption rate, SAR) and resulting temperature increase. This finding is practically highly relevant, since most existing safety standards limit SAR, the heating term, while they want to limit temperature. The difference is explained by tissue perfusion which provides an effective internal cooling mechanism that is not spatially correlated to the SAR distribution.

Objective 3, "to *assess the risk to human subjects from moving through the inhomogeneous stray fields of MRI scanners as these can induce slowly varying eddy currents inside the human body*" was achieved by the following results:

- Advanced computational tools were developed to determine motion induced low frequency fields and currents in anatomical body models by numerical simulations.
- The 2014 International Commission of Non-Ionising Radiation Protection (ICNIRP) guidelines request an 'exposure index' estimation for motion induced fields by applying a suitable weighting approach. These

guidelines are highly relevant as ICNIRP is the preferred source of reference for EU legislators. The project demonstrated that different weighting approaches, even though all guideline conforming, can give different results. This highlights the need for an amendment of the guidelines in this respect.
- The previously developed computational tools were applied in a broad investigation considering a variety of MRI magnets and realistic motion trajectories. The results showed: (i) no violation of the ICNIRP limits when the subject is performing common movements during clinical practice, (ii) a violation of the ICNIRP limits, in contrast, is possible when the subject moves abruptly in close proximity to the magnet.

Objective 4, *"to develop a validated measurement method suitable to assess the RF related hazards associated with emerging new MRI technologies such as parallel transmission or ultrahigh magnetic fields"*, was achieved by the following results:

- The advanced simulation infrastructure for RF safety calculations (see above) was applied to the case of ultrahigh fields (e.g. 7 T) where the field distributions become inhomogeneous and conventional safety measures fail. The measurement method based on calibrated RF field probes was utilized to validate the simulation results in this case, too.
- Radiation into the far-field is an additional possible dissipation path for RF power which must be correctly predicted by a numerical simulation. This mechanism is negligible at conventional field strengths but has to be accounted for at ultrahigh field strengths, i.e. 7 T or above. A method for the measurement of the radiated RF power at 7 T was devised and successfully tested. This way, the last missing quantity in the power balance equation became accessible and the metrological concept to provide traceable measurements of the RF electromagnetic fields associated with an MRI exam was completed.
- An additional challenge particular to pTx systems is the virtually unlimited number of possible set-points to be considered in a safety assessment. To reduce this complexity to a treatable level a strategy was improved and implemented, allowing to identify a small subset of the most critical pTx parameter settings. Any safety limits sufficient for these critical cases will automatically suffice for all other conditions possible. With this extra step it is now possible to apply the aforementioned safety concept based on validated numerical simulation to the pTx case, as well.
- The concept described above is generally applicable and valid. Its practical supervision requires some extra hard- and software, however, to analyse the state of the pTx system in real time and to perform on-the-fly comparisons with pre-set safety limits. An additional, simplified version of that pTx safety strategy was therefore developed. It is slightly over-conservative, i.e. deliberately sacrifices some performance, but can be implemented without the need for real-time measurements or simulations, making it robust, reliable, and compatible with existing and certified RF supervision hardware. With this approach it is much easier to demonstrate compliance with the relevant standards on MRI safety.
- It was stated before that potentially hazardous heating of tissue is the real concern about MRI related RF electromagnetic fields and this is unchanged when pTx considered. Soft- and hardware for very fast thermal simulations were thus implemented, allowing to assess the associated temperature rise for the large number of different pTx parameter settings. This gives much deeper insight into patient safety compared to electromagnetic simulations alone.

Objective 5, *"to develop a dosimetry method for emerging new MRI technology MRI guided radiotherapy, comprising a system for traceably measuring the absorbed dose to water for high energy photon beams in an MRI-accelerator combination"*, was achieved by the following results:

- An MRI compatible, transportable absorbed dose to water primary standard was produced and commissioned in conventional ^{60}Co and MV-photon beams.
- A benchmarking method for dose simulations in Monte-Carlo codes in the presence of a *B*-field was developed as a key value to the modelling and application of detectors in MRI-accelerators.
- For a subject in an MRI-accelerator, the relative biological effectiveness of radiation could, in principle, be modified by the presence of a magnetic field. Knowledge and understanding of such effects is a necessary prerequisite of any dosimetry concept and several potential mechanisms were investigated in detail:
  - Computations showed that the *scattering* of an individual secondary electron by a water molecule is not noticeably affected by the *B* field but processes involving *ionisation* do depend on *B*.

- An existing Monte Carlo code to model the track structure of secondary electrons in water was extended to include magnetic field effects, i.e. the Lorentz force and the ionisation effects just mentioned.
- Finally it was investigated whether the aforementioned effects of an external B field on the track of a single secondary electron result in a detectable *cumulative* effect on the number of DNA double strand breaks induced by single 6 MV or 15 MV photon and the result was that no cumulative effects were detectable. The project thus established that the Relative Biological Effectiveness of photons for radiation therapy are not affected by the magnetic field of an MRI scanner.

Objective #6, *"to develop concepts to assess the risks due to the presence of passive, metallic, medical implants inside the patient's body during an MRI scan*" ", was achieved by the following results:

- A concept was developed to qualify different positions of an implant carrying patient in the MRI scanner's RF coil as safe or critical. By a series of numerical simulations for an exemplary implant type, a hip prostheses, critical patient positions in the scanner were identified where tissue temperatures could exceed the permissible limit of 39 °C. Practically also highly relevant is the fact that regimes of safe positions could be stated where no noticeable effects of the implant are detectable and implant carriers can safely be scanned.
- Another important finding was the observation that tremendous simulation errors can result when a hip prosthesis is not accurately orientated within the computer model of a patient. In particular for long implants such alignment faults can easily occur. This hints at a principle limitation of present modelling approaches.
- In an extension of the original research program, tissue heating effects due to an MRI scanner's switched gradient fields were also investigated. The simulation results are alarming as they show that temperature rises of up to 3-4 °C can occur close to the implant. This raises serious concerns and calls for further investigations of this hitherto completely neglected aspect of MR safety.
- An approach was tested to reduce the danger associated with wire-like implants. A simplified model of a deep brain stimulator electrode was investigated and it was found that the local SAR at a critical point near the skull can be significantly reduced by using a high-impedance lead. This mitigation approach is helpful, therefore, but not sufficient since an alarming temperature increase of several degrees Celsius can still occur inside the brain, at the electrode tip.
- An MRI compatible sensor to measure RF currents induced in implanted electrodes was engineered and tested. Phantom measurements with this sensor were in good agreement with corresponding simulations. This indicates that such a sensor can serve two different purposes: for *risk assessment*, as it provides an independent and sensitive means to test the validity of simulation results; and for *risk management*, as it can serve as a watch-dog device to detect a critical situation during an MRI scan of a patient with implant.

Actual and potential impact

Dissemination

To ensure adoption of the project's outputs a wide range of activities were undertaken to disseminate the project's outputs to potential users. The consortium submitted 25 regular journal papers, 3 master theses and 33 peer-reviewed conference proceedings; 59 of these 61 publications are already published. A total of 47 papers resulted from co-operations with external partners, mostly from academia. It is clearly to be expected, that further publications will be written and submitted after the formal end of the project.

Project results were disseminated in 67 oral or poster presentations at scientific conferences, 53 of them for an international audience. Consortium partners (co-)organised twelve such events, ranging from highly focussed workshops for small specialist groups to international conferences with hundreds of attendees.

Consortium members were engaged in two internal training activities plus another eight courses or lectures for a general scientific audience. This included lectures at universities as well as hands-on training courses for other scientists. Complemented is this educational engagement by participation in 'Open Lab Days', 'Science Nights', and similar events for the general public.

Explicit stakeholder requests had initiated the MRI Safety project and close stakeholder interactions accompanied it all the way. Each project meeting was also a stakeholder meeting and the aforementioned workshop

organisations always implied stakeholder interaction. In addition, 23 direct meetings with stakeholders, often from industry, were held to discuss specific, project related subjects.

Consortium partners were active in four different national and international standardisation bodies which were regularly updated about the project results.

- IEC62B-MT40 working group maintaining the EN/IEC 60601-2-33 MRI standard;
- NA 080-00-08 AA / NA080-00 18GA, German mirror of IEC62B-MT40;
- Nederlandse Commissie voor Stralingsdosimetrie (NCS), bi-national Dutch/Belgium standardisation body for radiation dosimetry;
- CEI – TC 106 committee, Italian mirror of the IEC TC 106 technical committee.

Early impact

It will take years before the full impact of the MRI Safety project is achieved and can be assessed. Nevertheless, there is some 'early impact' which can already be reported.

- Representatives from Elekta, leading European manufacturer of radiotherapy equipment, confirmed in March 2013 that "*... The EMRP project HLT06 contributes exact and reliable radiation dosimetry to this endeavor, an indispensable precondition before any patient can be treated. Thanks to EMRP results manufacturers Elekta were in the position to make the next step...*" i.e. bring the system to the market.
- Project partners from Turin developed a new formulation to calculate motion induced electromagnetic fields in the human body. Australian colleagues recognized the value of that approach and a fruitful co-operation emerged, resulting in three journal papers and two conference proceedings, so far.
- Scientists from the Berlin Ultrahigh Field Facility expressed interest in the methodology developed for metallic implants in MRI. In collaboration with the consortium they used the simulation methodology and equipment developed in the project to systematically investigate and validate the potential safety hazards of cardiac stents in MRI, resulting in one journal publication and three conference proceedings.
- Representatives from *Bundesamt für Strahlenschutz*, the German authority for radiation protection, and ICNIRP closely followed and interacted with the project from the start. Findings from the motion-induced field work affected certain statements in the guidelines. But the most important effect of the collaboration, according to an ICNIRP expert, was the fact that it helped them to sharpen their view and get confidence in their physical picture of the problem, thus supporting them in devising their new guidelines (Health Phys. 106, 2014, 415-25). Vice versa, project scientists benefitted a lot from these intense discussions and the publication of the guidelines affected further project activities in that field.

In addition, some recent developments can be reported which were not *caused*, but supported by the MRI Safety project.

- In 2015 the 2nd amendment to the IEC-60601-2-33 was voted upon and unanimously accepted. This amendment will allow, for the first time, CE marking of 7T MRI scanners thus paving the way for ultrahigh field MRI into the clinical routine. The consortium was represented on the maintenance team for the IEC standard and also on one national mirror committee which was voting on the new amendment.
- Shortly after, leading European MRI manufacturer Siemens announced their decision to actually take that step and to develop the first *clinical* (CE marked) 7T scanner, thus making this high-end technology finally available for patients.
- For 2015, the German Research Foundation (DFG), launched two funding programmes centred on MR guided radiotherapy. This documents high expectations and confidence in such new technology.

Addressing end-user needs

In its 2011 Research Agenda the World Health Organisation (WHO) stated a number of “high priority research needs" with respect to EMF dosimetry (i.e. including MRIs) for example to "*assess characteristic RF EMF emissions, exposure scenarios and corresponding exposure levels for new and emerging RF technologies and for changes in the use of established technologies: This work should address the latest developments in areas such as ... body imaging*". This request was successfully addressed as the project made a number of significant dosimetric contributions addressing the specific case of MRI. Methods were developed to assess characteristic MRI related RF emissions in general and in particular for emerging technologies/changes in use of existing technologies like ultrahigh fields (e.g. 7T MRI scanners) and pTx.

The latter two technologies are innovative developments in MRI but pose new safety hazards. Project results show that these hazards can be successfully contained, which helps not only to protect EU citizens but also supports the technology leading EU manufacturers in bringing these innovations into the clinical routine.

Almost 10 % of the European population are carrying medical implants but no clear metric existed to assess this safety hazard in MRI. To develop such a metric is a long-term task but a few first steps in this direction were achieved within the project. The investigation of exemplary implant types with numerical simulations and the development of sensors capable to measure potentially hazardous induced currents in wire-like implants are relevant contributions to the development of such a metric.

The 2004/40/EC directive was aimed at health and well-being of employees but unintentionally almost banned MRI as it was argued that exposure limits were already exceeded when a worker approaches the scanner. The project addressed this problem by providing the proper numerical techniques to quantify the exposure in terms of induced electric fields and current densities inside the body. It was shown that it is indeed possible to exceed the limits as given in the most recent guidelines. It is now up to legislators to draw conclusions on these findings as only unpleasant, temporary sensations but no truly adverse health effects result if the guideline limits are exceeded.

MRI-accelerator combinations are an exciting new development with the potential to revolutionize radio-therapy of cancer. However, no traceable dosimetry existed for this application but is a required precondition before patients can be treated. The project provided such traceable dosimetry and was of utmost importance, therefore, for large European MedTech companies pursuing the development of the MRI-accelerator.

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