21NRM05 STASIS

Publishable Summary for 21NRM05 STASIS
Standardisation for safe implant scanning in MRI

Overview

Magnetic resonance imaging (MRI) is the gold standard for medical diagnostics with more than 40 million MRI scans performed in the European Union (EU) every year. Whereas this number is further increasing, scanning of patients with implants still poses a safety hazard. Even though international standards exist to address these risks, improvements are urgently needed and called for by implant manufacturers, Magnetic Resonance (MR) manufacturers and convenors of MR safety standards. This project aims at updating and improving the relevant standards providing clinicians with more confidence when scanning their patients, and implant and MRI systems manufacturers with novel methods to implement safety strategies for safe implant scanning.

Need

Medical implants are a 3 billion € market in the EU, with approximately 50 million citizens carrying one or more. Implants can be generally categorised into active implantable medical devices (AIMDs) or passive implants. Active implants (e.g, neurostimulators, cardiac pacemakers, implanted infusion pumps or internal defibrillators) require power to operate and have embedded electronic circuits that fulfill a specific function. Passive implants (e.g. hip or knee prostheses, stents, aneurysm clips or screws) do not require an external power source.

Due to comorbidity effects, 60- to 80-year-old have the highest probability of both needing an implant and an MRI. With an aging population, these numbers are likely to further increase. Metallic implants in a patient's body are a safety hazard in MRI, since interaction of the conductive device with the MR scanner's strong electromagnetic fields can result in dangerous tissue heating. Demonstrating compliance with MRI safety, in particular with respect to heating effects, is a challenging process with high product liability risks for implant manufacturers.

At present, regulators assess MRI compliance based on i) *in silico* test results, ii) knowledge of the expected electromagnetic fields in the patient body, and iii) history of the MR safety of similar products in service. But this is not based on quantified *in vivo* data, and it does not establish the risk to the patients. As a consequence, device manufacturers are unable to readily determine whether their device will be compliant prior to submission to the regulator. Therefore, future 'smart' implant technologies for medical and non-medical use are needed. 'Smart' AIMDs equipped with simple, small, and cost-effective sensors, could communicate with a parallel transmission (pTx) capable MRI scanner. It has been demonstrated that pTx is capable of steering radiofrequency (RF) electric fields away from the implant, thus substantially reducing hazardous tissue heating, still maintaining the imaging quality at a level comparable to the implant-free case. Additionally, because the EU's Medical Device Regulation (MDR) demands that medical implants and MRI scanners adhere to harmonised standards, improvements to such devices will only have a tangible impact once incorporated into standards.

Heating of bulky metallic passive implants due to MRI switched gradient fields demonstrated, in some cases, to exceed RF induced heating posing an often-unrecognised hazard for implant carriers. Some normative documents, e.g. ASTM F2182 ignore this effect completely, while others, e.g. ISO/TS 10974 are limited in scope just to those implant categories where that effect is least relevant. Therefore, a dedicated methodology must be developed to address this issue.

Report Status:
PU – Public, fully open

Publishable Summary

Issued: August 2023

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or EURAMET. Neither the European Union nor the granting authority can be held responsible for them.

The project has received funding from the European Partnership on Metrology, co-financed from the European Union's Horizon Europe Research and Innovation Programme and by the Participating States.

European Partnership Co-funded by the European Union

METROLOGY PARTNERSHIP EURAMET

At an international stakeholder workshop organised by the predecessor EMPIR project 17IND01 MIMAS, convenors and chief representatives for the three most relevant standards on implant safety in MRI (ASTM F2182, ISO/TS 10974, and IEC 60601-2-33) expressed the need for further work on a metrologically sound assessment of all uncertainties and risks associated with implant safety in MRI; development and documentation of standardisation-compatible test procedures; open-source hardware, design concepts and ideally prototypes of suitable testing hardware; as well as guidelines for *in vitro* testing of gradient-induced heating of medical implants.

Objectives

The overall objective of the project is to support standardisation for safety assessment of medical implants in MRI scanners. Medical implants can refer to passive implants (e.g., orthopaedic prostheses) or active implants (e.g., cardiac pacemakers or deep brain stimulators). Specific objectives are:

1. To develop, evaluate and explore the uncertainty (maximum tip E-field, SAR or temperature) of an implant safety concept in MRI comprised of sensor-equipped smart medical implants (e.g., pacemakers or neurostimulators) and pTx capable MRI scanners to assess and mitigate *in situ* RF induced implant heating. In addition, to formulate technical specifications for sensor-equipped smart medical implants and a communication interface between such implants and an MRI scanner.
2. To develop open-source reference hardware and traceable measurement procedures that allow testing of implants (mainly active) under pTx MR conditions. In addition, to develop, design and build a preliminary version of an open-source reference system of a pTx body coil and RF transmission hardware, suitable for offline implant testing by manufacturers and test houses.
3. To develop standardised measurement procedures for the interaction of bulky passive metallic implants with RF fields and alternating gradient coil magnetic fields in the kHz range. In addition, to provide guidelines and technical specifications for comprehensive *in vitro* testing of gradient-induced heating of such implants.
4. To contribute to the standards development work of ISO 10974, ASTM F2182 and IEC 60601-2-33 to ensure that project outputs are aligned with the needs of these bodies, communicated quickly to those developing the standards and to those who will use them (MRI and implant manufacturers, test houses) and in a form that can be incorporated into the standards at the earliest opportunity.

Progress beyond the state of the art and results

Objectives 1 and 2

Physical sensors on implants are not at all uncommon, e.g., they are used to determine the stimulation threshold of a pacemaker. However, their application to ensure patient safety in MRI certainly is. The concept of sensor-equipped smart medical implants in conjunction with pTx capable MRI scanners is a potentially disruptive approach to assess (via the implant sensor) and mitigate (via the scanner's pTx system) RF induced implant heating in MRI in situ. At present, only the implant is characterised by an assessment which is completely off-line (temperature and field measurements in homogeneous liquids or gels and numerical simulations of human voxel models). The proposed sensor-based assessment replaces most of the extensive off-line characterisation of the implant by a careful sensor calibration. Once this is done, the crucial question whether or not an MRI scan is safe needs no longer to be decided off-line, based on phantom measurements or some generic voxel models. It will be decided in situ, i.e., for the given patient, with a given implant, lying in a specific position in a given MRI scanner with a specific MR sequence to be run. More importantly, the responsibility for the scan is transferred: both the implant manufacturer and the scanner manufacturers assume the full responsibility (with well-defined and well separated roles), while the MR operator just gets a push-button solution.

Implant reference hardware with sensor-embedded hardware has been designed and used in first calibration measurements using external E-field and temperature sensors. A simulation setup has been generated and validated against field and temperature measurements. This simulation and testing environment allows

calibrations of sensor-equipped implants and can be translated to investigate various clinical RF exposure scenarios. A wireless communication workflow has been established connecting implant reference hardware and a commercial 3T MRI scanner. Transmission speed, data rate and data volume were adjusted to reach on-the fly transmission of safety relevant information and use this information to suppress RF induced heating at the implant tip. This setup was tested under varying conditions in realistic exposure settings.

Objectives 3 and 4

Previous investigations demonstrated that in certain cases the gradient-induced heating of an implant during an MRI scan can be even more hazardous for the patient than RF induced heating. For active implants some guidance exists in the ISO/TS 10974 to test gradient coil (GC) heating of implants; however, this methodology needs further extensions. At the same time, the ASTM F2182 standard, which is widely adopted for safety testing of passive metallic implants, does not provide any guidance at all. These critical gaps need to be filled and test houses need validated and efficient procedures to assess gradient induced heating of implants.

Digital models and physical implant samples have been collected from implant manufacturers. Worst realistic exposure scenarios have been investigated for each implant. The results show that ISO/TS 10974 procedures overestimates the peak temperature increase up to 10 times. This fully justifies the development of a Tier 2 approach to improve the procedure proposed in the ISO/TS 10974 standard for orthopaedic implants. An efficient procedure to compute the temperature increase induced on an implant by a homogeneous, harmonic magnetic field, arbitrarily oriented in space, has been devised. The procedure also allows to analytically compute the direction of the magnetic field that maximises the implant peak temperature increase answering to a present ISO/TS 10974 testing requirement. Accurate virtual surgeries have been carried out and the digital models are now ready to be used for simulations aimed at comparing gradient-induced and RF-induced heating.

Outcomes and impact

To date the project has contributed to one publication (https://doi.org/10.1002/nbm.4900.) and 8 scientific conference papers. Berk Silemek and Johannes Petzold both from PTB, received the 1st and 3rd poster prize from the ISMRM Study Group on MR Safety for their conference posters at the ISMRM in Toronto, Canada on STASIS related work. Discussions on STASIS related project results including stakeholders from MR and implant manufacturers and scientific and clinical community were held at the STASIS stakeholder meeting and Sim4Life workshop in June 2023 in Toronto, Canada and at the IEC SC 62B MT40 standardisation meeting in May 2023 at the PTB in Berlin, Germany. Educational activities so far included a training course on MR dosimetry in MRI organized by INRIM for PhD students at the Politecnico di Torino, Italy. Repositories under open-source software and open-source hardware licenses were created and published on the reference implant hardware (https://gitlab1.ptb.de/mri-lab/reference-wireless-implant) and gradient induced device heating simulations (https://github.com/umbertozanovello/Sim4Life-ISO10974_gcHeatingAnalysis. Furthermore, a webpage (https://www.ptb.de/stasis) was generated and is regularly updated with project related activities.

Outcomes for industrial and other user communities

This project will directly support implant and MRI manufacturers as well as testing laboratories or regulatory bodies. Implant manufacturers are currently submitting applications for the approval of MRI safe or conditional safe implants, and the regulators are approving these applications according to the ISO/TS 10974 or the ASTM F2182 despite the recognised gaps. The project will close many of these methodological gaps and contribute to updated, improved and new standards. Development costs for the implant industry will be reduced and possibly overpriced costs for recalls or liability claims avoided.

The communication workflow for a novel safety concept developed on smart medical implants will furthermore dissolve the current stasis in safety and innovation around MR compatible implants and will speed up innovation both on implant and MR innovation side. The generic open-source implants and procedures produced, will enable simple validations of these concepts, and enable validation of product prototypes without the need to share proprietary information.

Project participants or affiliates MR: comp and ZMT will be the first test houses to commercialise new or upgrade existing products and services in implant safety testing, but others will follow, as all technical descriptions will be freely available. Implant manufacturers will then benefit from a variety of commercial facilities offering the new state-of-the art in implant testing.

Advantages of implant and MR scanner communication are not limited to safety application. They rather enable multitude of synergistic applications, including MR sequences utilising the implant sensor information to adjust imaging parameters (e.g., triggering for cardiac imaging by pacemakers' signals or using the sensor measurements of neural implants alongside high resolution functional MRI acquisitions) for advanced scientific and diagnostic results.

Outcomes for the metrology and scientific communities

All measurement hardware (test artefacts and technical design files) and methodology in this project will be easily accessible and reproducible through open-source publications and maintenance. Participating NMIs as well as national and industry measurement laboratories across Europe will thus be enabled to provide the traceability for all measurements during the MRI safety assessment of an implant. This will also enable to pick up safety assessment methodologies developed in the project, to expand and extend them and to translate them to future normative work.

Outcomes for relevant standards

There is an intense standardisation effort on implant safety, including heating from RF and gradient coils, involving many standardisation bodies (ISO, CEN, ASTM, NEMA). The most far-reaching standardisation document, ISO/TS 10974, however, has many open questions that must be answered. As members of this consortium are on the standardisation group and have contributed significantly to the development of the Technical Specifications, the results of this project will directly benefit the development of the standard. Significant results of the project will be summarised and inserted into the ISO/IEC joint working group over the project timeline.

The consortium has also been equally involved in the major revision of IEC 60601-2-33, that also considers the special conditions of passive and active implants and multi-channel transmission. The consortium will provide project input to this Committee that can be directly utilised in the planned amendments of this standard. The MT40 maintenance team of the IEC 60601-2-33 and the Joint Working Group developing the ISO/TS 10974 have mandated this project.

While ISO 10974 is addressing active implants with respect to gradient induced heating, the ASTM F2182 is applied for passive implants. No guidance towards safety testing of gradient coil induced heating is found in the standard. The consortium members are in the standardisation group and will provide input to the committee. As an outcome of the project a comprehensive standard testing procedure will be formulated and submitted as a work item to a current ASTM standard committee, such as ASTM F04.

Longer-term economic, social and environmental impacts

- Drive innovation, provide legal certainty, and improve market opportunities for implant manufacturers.
- Strengthen the position of MRI manufacturers as technology leaders in their fields.
- Provide better and safer access to MRI for implant carriers.
- Improved safety standards (ISO 10974, IEC 60601-2-33, ASTM F2182) and guidance documents.
- Implant manufacturers will benefit from faster development and market introduction of their innovative products
- MRI manufacturers will benefit by new applications for their innovative developments in parallel transmission technology.
- The mostly overlooked hazard due to gradient induced heating of metallic non-active implants will be finally addressed in the relevant standards.

- Overly conservative safety measures that limit imaging performance both for RF and gradient induced heating can be avoided leading to better image quality in the presence of implants, which is needed for diagnostic purposes.
- The healthcare systems in the EU will benefit from cost reduction by the proposed smart implants approach, i.e., shorter times for risk assessment and MR scan time reductions due to improved imaging performance in the presence of implants
- The work will facilitate the inclusion of implant MRI compatibility in future revisions of the EU Medical Device Regulations, enhancing the safety of EU citizens bearing implants.
- The applied dissemination of the project results as open-source hardware follows the recommendations towards the U.N: sustainable development goals (SDGS). International organisations and governments can increase their innovation capacity through open hardware, which can build innovation capacity in countries with low investments in science, technology and innovation, it enables new multi-stakeholder partnerships and collaborations between academia, civil society and the private sector, it makes science more transparent and participative, supporting global decentralised collaboration. In addition to that, international organisations can promote open hardware by incorporating it into their strategies, aligning incentives and raising awareness through education and training.

List of publications

Petzold, J. et al (2023) 'Towards an integrated radiofrequency safety concept for implant carriers in MRI based on sensor-equipped implants and parallel transmission', NMR in Biomedicine, 36 (7) e4900. Available at https://doi.org/10.1002/nbm.4900.

This list is also available here: https://www.euramet.org/repository/research-publications-repository-link/

<table>
<tr><td colspan="2">Project start date and duration:</td><td>01 October 2022, 36 months</td></tr>
<tr><td colspan="3">Coordinator: Lukas Winter, PTB Tel: +49-3481-7573 E-mail: Lukas.winter@ptb.de
Project website address: https://www.ptb.de/stasis/</td></tr>
<tr><td colspan="2">Chief Stakeholder Organisation:
ISO TC150/SC6/JWG2</td><td>Chief Stakeholder Contact:
Michael Steckner</td></tr>
<tr><td>Internal Beneficiaries:
1. PTB, Germany
2. CMI, Czechia
3. INRIM, Italy</td><td>External Beneficiaries:
4. DKFZ, Germany
5. MRC, Germany
6. STU BA, Slovakia</td><td>Unfunded Beneficiaries:</td></tr>
<tr><td colspan="3">Associated Partners: 7. ITIS, Switzerland</td></tr>
</table>