1. Publishable summary

Project context and objectives

In recent years MR-guided focused ultrasound surgery (MRgFUS) has become a frequently applied means for the treatment of fibromyoma of uterus and of bone metastases. MRgFUS combines high intensity focused ultrasound for thermal ablation of diseased tissue with MR imaging to visualise the tumour and surrounding anatomy and to provide MR thermal feedback.

Treating tumours in moving organs with MRgFUS however presents tremendous technological challenges including motion due to breathing and shielding of the target by the rib cage. The VPH project FUSIMO (2011-2014) aimed at the development of a planning system for MRgFUS capable to deal with the challenges in the treatment of moving abdominal organs.

TRANS-FUSIMO will translate the FUSIMO results into a clinically applicable system spanning the full clinical workflow of planning, conducting and assessing as well as learning from the procedure. With such an integrated system, MRgFUS can become a commercially and clinically competitive alternative to current surgical and minimal-invasive oncological interventions, thus providing a non-invasive treatment, reducing side effects and healthcare costs. The particular objectives for the TRANS-FUSIMO project are:

- Extension of the FUSIMO demonstrator to support conducting and assessing of the intervention under breathing motion,
- Interfacing state-of-the-art FUS hardware and imaging devices to build an integrated real-time-capable system for liver FUS,

TRANS-FUSIMO – Clinical Translation of Patient-Specific Planning and Conducting of FUS Treatment in Moving Organs

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Stiftelsen SINTEF (Norway) – SNF

Eidgenössische Technische Hochschule Zürich (Switzerland) – ETH

Medical Imaging Research Institute Mediri (Germany) – MED

IBSmm Engineering (Czech Republic) – IBSMM

InSightec Ltd. (Israel) – INS

GE Medical Systems Ltd. (Israel) – GE

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Johann Wolfgang Goethe Universitaet Frankfurt (Germany) – UOF

Universita Degli Studi Di Palermo (Italy) - UOP

Timetable:

January 2014 to December 2018

Total cost: € 5,617,995.00

EC funding: € 4,049,999.00

- Improving model components for optimized clinical workflow, real-time applicability and validated outcome prediction,
- Allowing training and learning using the TRANS-FUSIMO software system by building a case and results database,
- Conducting of pre-clinical (phantoms, cadaver, animal) experiments with the TRANS-FUSIMO system.

In a clinical trial, the feasibility of using the integrated system for neoadjuvant MRgFUS to achieve prolonged survival will be investigated.

The main emphasis of the TRANS-FUSIMO project lies on the implementation and validation of a real-time control system that is able to control the following hardware devices:

- MR hardware for acquisition of anatomical and thermometry data,
- FUS hardware for generating and focusing high intensity ultrasound,
- Ultrasound tracking for tracking the movement of liver and ribs,
- Robot arm for placement of the ultrasound transducer on supine patients.

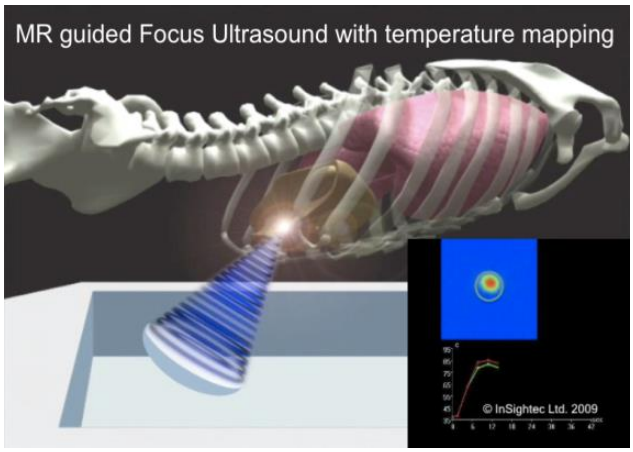

Figure 1: Ilustration of abdominal FUS

Starting with interfacing the MR hardware the TRANS-FUSIMO control system will be able to get real-time images from the MR device. It will also be investigated to use the MR for real-time monitoring of the motion of the breathing patient in order to get information as accurate as possible and to get real-time information about the rising temperature in the body. Another possibility to track the target area is to use a diagnostic ultrasound device with real-time capability. With this information and a statistical motion model developed in FUSIMO, the steering of the FUS hardware can be performed. Thus, the TRANS-FUSIMO control system will have also the ability to communicate real-time motion information to the steering server provided by the FUS hardware company InSightec. The last hardware component is the robot arm which will place the transducer at the beginning of the procedure.

After finishing the hardware developments, TRANS-FUSIMO performs preclinical tests as well as an animal study. In a later stage of the project a first patient study will be conducted with patients under breathhold, i.e. without breathing motion. In the last phase of the project a clinical trial with patients that are treated with MRgFUS under breathing motion will be conducted.

To enable clinical personnel to train and learn MRgFUS therapy and the TRANS-FUSIMO system, a training and learning system is implemented on the basis of patient-specific models and data recorded during interventions. This training will be available outside of the MRgFUS therapy room but can also serve as a reference and simulation support database just prior to or during preparation of a therapeutic procedure.

Work performed during the reporting period, main results

In the first period of the TRANS-FUSIMO project the consortium was focussing on the following objectives:

- Setup a basis for quality assured software development to be used for the TRANS-FUSIMO integrated control system
- Definition of integration of all components
- Model improvements
- First steps towards a training simulator and database of relevant clinical cases
- Ethical approvals for preclinical and clinical trials
- First validation experiments
- Dissemination of information about the project in the scientific community as well as the general public

The main results of the first year of TRANS-FUSIMO can be divided into two major parts: Technological and clinical results. The technological results include the specification of an integrated control system that will control different hardware. Therefore, the APIs (application programming interfaces) have been developed in the first year. The quality assurance for this medical device was initiated according to ISO 62304. An integral part of the use of this medical device in a clinical study is the testing and validation of single components and the overall integrated system. First validation experiments have been conducted during this period. The models developed in FUSIMO have been also improved during the first year. However, especially in view of the real therapy scenario specific motion models have to be developed during the next period of the project. To train the clinical personnel before a liver MRgFUS intervention, we started to work on a training simulator and a database of relevant clinical cases.

The main clinical results of the first year of TRANS-FUSIMO include the specification of parameters relevant for preclinical and clinical validation of the TRANS-FUSIMO software assistant and the work on ethical guidelines and ethical approvals for preclinical study and study phase I which also includes a necessary volunteer study to investigate the breathing motion of the liver in more detail.

Another important result of the first year is the accession of University of Palermo as a new project partner. University of Palermo will perform the animal study.

To raise awareness for the research topic and the TRANS-FUSIMO project in particular and to build links to the scientific community, dissemination activities play a particularly important role for the TRANS-FUSIMO project. Therefore, several contributions to international conferences and workshops have been made. Also, a public website has been set up and the project has been featured on Twitter. In scientific sessions, dedicated symposia and exhibition booths of several congresses in the field, the TRANS-FUSIMO project has been presented to the scientific medical-radiological and technical-engineering communities.

Expected final results and potential impact

The expected outcome of the TRANS-FUSIMO project is a real-time capable control system for MRgFUS procedures in moving abdominal organs, especially in the liver. The system will be validated during a preclinical animal trial and a clinical trial. In combination with an extended version of the FUSIMO demonstrator and a training and learning tool, TRANS-FUSIMO covers the whole pipeline for MRgFUS liver interventions: new clinical personnel is able to train such procedures by means of previous cases, actual cases can be planned and a real-time control system enables the physicians to treat the patients during free breathing.

The long-term impact of TRANS-FUSIMO lies in improving the treatment of cancer and metastases in a variety of organs and for a wide range of patients. This will contribute to substantially reducing the estimated 1.7 million deaths in Europe each year. The reduced side effects (compared to conventional surgery, systemic chemotherapy and radiation therapy) of the MRgFUS will reduce complications and consequently lead to a higher quality treatment of the patients at lower financial demand for health insurance and social welfare.