RESEARCH NEWS

Fraunhofer MEVIS paves the way for new MR sequences in clinical practice

Accelerate and Optimize MRI Examinations

With the gammaSTAR software platform and the SpinIt project, researchers at the Fraunhofer Institute for Digital Medicine MEVIS are facilitating the transfer of innovative imaging technologies into routine clinical use.

Magnetic resonance imaging (MRI) is one of the most important imaging modalities in medicine. Continuous advances in scanner control software, known as MR sequences, have the potential to deliver more informative images and significantly faster examinations. However, complex regulatory pathways often hinder the successful transfer of new sequences into clinical routine use. Researchers at the Fraunhofer Institute for Digital Medicine MEVIS in Bremen are now addressing this gap. With the software platform gammaSTAR and the SpinIt project, they are working together with industry partners to transfer innovative MR sequences systematically into clinical applications in a manufacturer-independent and quality-assured manner. This should benefit patients and clinics.

The diagnostic value of an MRI scan depends critically on the MR sequences used. These sequences define when and how radiofrequency pulses are transmitted; magnetic fields are switched, and signals are read out within the scanner. "An MR sequence precisely defines how the various components must be controlled over time to create the desired image contrast," explains Daniel Hoinkiss, Principal Scientist at Fraunhofer MEVIS. "This fine control must operate with extremely high accuracy and is therefore very challenging to develop."

But the effort is worthwhile: These sequences promise, for example, shorter examination times or novel image contrasts that can improve diagnostic precision. "One focus of current developments is on sequences that accelerate the scanning process and reduce examination times from half an hour to just a few minutes," says Hoinkiss. As a result, patients could spend less time in the confined scanner bore, while clinics could more efficiently employ their equipment.

Simplify the certification process

Despite this potential, the path from new MR sequences to routine clinical use is often challenging. To date, sequences have been typically programmed within manufacturers' proprietary development environments and approved together with the corresponding hardware. "For specialized or novel approaches, this barrier is often difficult

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to overcome," Hoinkiss explains. "Our aim is to simplify and, in a sense, democratize the certification process, making it more accessible for third-party providers."

To this end, Fraunhofer MEVIS initiated SpinIt, a project funded under the EXIST program of the Federal Ministry for Economic Affairs and Energy. The project aims to support start-ups and research groups in obtaining certification for new MR sequences and to use them on different MRI systems. The starting point is gammaSTAR, a software platform developed by Fraunhofer MEVIS, which enables manufacturer-independent implementation of MR sequences and their execution on different MRI systems via standardized drivers. Researchers can develop sequences in gammaSTAR without having to learn and work with manufacturer-specific programming languages. "We designed the platform in such a way that MR sequences already meet a quality standard that fundamentally allows for subsequent medical device approval," says Nora-Josefin Breutigam, who is responsible for quality and partner management. Within the SpinIt project, the Fraunhofer team is further developing gammaSTAR with a specific focus on certification. The objective is to establish a clear, reproducible process that allows MR sequences developed in research to be approved as medical devices. "This is pioneering work," Breutigam emphasizes. "To date, there has been no case in which a third-party MR sequence has been approved independently of the manufacturer."

Regulated access for third-party providers

A key role in this innovation process is played by industry partner Siemens Healthineers. The medical technology company supports this type of open innovation by providing a certified interface for external software solutions. "With this interface, we can approve MR sequences as medical devices and bring them into clinical routine use," says Breutigam. This would, for the first time, create regulated access for third-party providers, including research groups and start-ups.

The path toward this goal is complex and requires extensive documentation as well as systematic testing. "We simulate our sequences and check, for example, whether left and right are correctly assigned," explains Simon Konstandin, who is responsible for technical development. "This sounds trivial, but a single incorrect sign can result in swapped sides, which could lead to misdiagnoses in clinical application." Such errors must be reliably excluded before a sequence can be used routinely in clinical practice. This process not only concerns the MR sequence itself, meaning the control of hardware during data acquisition, but also the subsequent reconstruction of image data. It is only through these reconstruction algorithms that medically interpretable images can be generated from raw data. "An MR sequence is always a package consisting of imaging and reconstruction," Konstandin emphasizes. Accordingly, both components must be jointly quality-assured, tested, and certified, as errors in reconstruction could have serious consequences for diagnosis even if the measurement itself is performed correctly.

New approach facilitates multicenter clinical trials

The new approach also offers particular benefits for multicenter clinical studies. At present, comparable datasets can usually only be obtained by using identical MRI systems or by aligning different measurement protocols through complex coordination processes. Even then, the results are often unsatisfying. "With system-independent sequences and identical reconstruction, different devices could be used while achieving significantly better comparability," says Breutigam. "Even simplifying the preparation of such studies alone could lead to substantial cost savings in the future."

At the end of the 18-month EXIST funding phase, it will be decided whether SpinIt will result in a spin-off that operates as a service provider for the approval and quality assurance of MR sequences. "Our short-term goal is to make innovations from research accessible for clinical use in the first place," Hoinkiss summarizes. For patients, clinics, and researchers alike, this represents an important step toward ensuring that new MRI concepts reach clinical practice more quickly, where they are needed.

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Picture 1: gammaSTAR: A vendor-neutral MRI framework to develop, simulate, and reconstruct sequences, speeding up development and ensuring consistent imaging across scanner models.

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Picture 2: Conceptual representation of the vendor-neutral MR sequence development platform gammaSTAR

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