Potential Clinical Applications for Ultra-High Field MRI

Michael V. Knopp MD, Ph.D.; Wright Center of Innovation in Biomedical Imaging, The Ohio State University, Columbus, Ohio; E-Mail: knopp.16@osu.edu

Ultra-High Field, 7T MRI is rapidly evolving both in its technology as well as in its potential medical applications. Currently there are globally about 40 clinically capable ultra-high field MRI systems installed with a rapidly increasing trajectory of installations. As the current systems are not “FDA” or “regulatory agency” approved from any manufacturer, all patient studies have to be considered to be investigational at this point in time.

We operate under a tiered IRB protocol setup that consists of a master and many affiliated IRB approved protocols. Over the operational experience, it is becoming increasingly evident that we are near the point that 7T imaging provides unique capabilities in the broad field of neuroimaging, neuro-oncology, neuro-functional and musculo-skeletal imaging. Special applications such as imaging of the eye, traveling wave, multi- or alternate nuclei imaging and UHF MR spectroscopy are being demonstrated. These methodological developments are also evolving in a way that they can provide information that has the potential to be included into patient care decisions.

Even if our own community frequently appears to be hesitant to integrate new methodologies into clinical decision making, our surgical and other partners will rapidly adapt because there is no alternative information available. We therefore need to deal not only with legal, compliance and safety issues; we also need to address ethical and economic aspects. This exciting progress quickens the need on how to deal with those challenges of providing potential clinical care on a currently investigational device.

We operate a 7T MRI system (Philips Achieva, Cleveland, Ohio) since 5 years, and previously a prototype 8T for 7 years, with a focus on translational and clinical applications. The current facility is located within a large clinical outpatient facility with multiple other imaging systems adjacent and is fully JCAHO compliant for human patients. Furthermore, the facility is designed to also enable veterinary patient and pre-clinical imaging services. Staffing for licensed technologist and nursing support is also available.

In our opinion, ultrahigh field MR imaging is on a trajectory to become a clinical reality for specific situations. There is other precedence in medical imaging such as the evolution of PET that can serve as a roadmap concept for this challenge. Also, the more awareness and coordination is on this challenge in our community, the better we can facilitate access to advanced UHF MRI capabilities for specific patients needing those while we continue to develop our technology and methodology.

Let us first discuss where UHF 7T MRI could fit into the clinical application paradigm. To start, it will only be appropriately applicable, if we have a definite benefit in clinically relevant information that is meaningful either for disease detection, characterization, therapeutic interventions or monitoring biologic effects of therapeutic approaches. In a nutshell, “me too” will not be sufficient, we will need to expect and deliver substantive, additional, impactful and clinical relevant information. With this high bar set on expectations towards 7T UHF MR clinical imaging, we can focus on the current opportunities. UHF MRI has unquestionable a head-start on the morphologic and structural resolution even compared to 3T MRI. If we use this and combine it with increased signal sensitivity to add quantitative and functional information, we have the opportunity to quickly reach a substantial gain in clinical information that can match the above stringent expectations. For example, using 7T UHF MRI in mapping the neuro-anatomic targets for neuro-modulation therapy (Deep Brain Stimulation) and combine it with neuro-functional and neuro-connectivity assessments as well as neuro-navigation, we can establish a most impactful imaging procedure that leaps beyond current capabilities. This and applications like it are quickly becoming “no-brainers” that these are clinical applications. Taking these expectations and applying those to imaging of cartilage, for example the knee, show that those

also could readily become a fully justified approach as the combination of outstanding morphologic resolution and with quantitative methodologies such as gag-CEST can provide a comprehensive and detailed information otherwise currently not achievable. However, we also need to be able to utilize the refined or improved information to impact the therapeutic approach and patient outcome in a substantive way. Our UHF community does need to learn from the PET community, that we can only drive clinical adaptation, if we demonstrate unequivocally the impact, safety and outcome or in regulatory terms, the traditional concept of efficacy and safety.

Let us now review UHF safety, patient studies have been performed under IRB protocols now for more than 12 years after the very first feasibility studies using a prototype 8T at OSU were reported in 1998. The FDA has classified MRI up to 8T as non-significant risk and cumulative more than 10,000 UHF human examinations can be estimated to have been performed in the last decade with no increased serious adverse event characteristics than with lower fields. We can summarize at this point, that the most commonly used UHF 7T passive shielded MRI system have continued to demonstrate an excellent safety profile that is fully compatible with expanded clinical utilization.

From a technology perspective, we believe that the advances in parallel, multi-channel acquisition have been essential and the advent of combining with multi-transmit approaches will achieve image quality, robustness and reproducibility essential for clinical application performance expectations.

Lastly, let us discuss some perspectives on the economic implications. Again, we like to start with the comparison of the early days of positron emission tomography (PET) where the economic realities appeared to preclude a clinical adaptability, however history has demonstrated that it evolved into one of our most effective and important cancer imaging and response assessment methodologies in patient care. Having said this, UHF 7T MRI is not 3T MRI on “steroids”, it is a fundamentally more advanced and more complex approach. On the one hand it is justified to argue, why should a 7T imaging study not be reimbursed as our other clinical care MR imaging studies, if it delivers at least equivalent information? While this seams trivial, it is a major issue that leads to current patients having to have a clinical care 1.5T or 3T in addition to an “investigational” 7T MRI, even if all the relevant clinical information is already available on 7T UHF imaging. On the other hand, it is also an appropriate expectation, that if UHF 7T imaging can provide clinical relevant information that is not otherwise non-invasively available, should it not be reimbursed at an increased level aligned with its increased clinical contribution? This also seems reasonable and many analogies can be found in medicine. In summary, we believe that our community needs to champion a two tier approach, one that UHF 7T imaging can be reimbursed as equivalent to other clinical care imaging if equivalent information is being provided (even if this approach will never fully cover the full cost of a 7T system and operation); and second, an elevated reimbursement to recognizes the additional, unique and clinically impactful information provided by an advanced UHF 7T methodology. As an analogy, surgeries all use surgical approaches and are reimbursed based on their complexity and appropriateness, so why do not we also evolve these concepts in MR imaging?

7T MRI can become a clinical reality for specific indications and our prediction is that it also will be a reality however the issues discussed have to be appropriately addressed and validated. UHF 7T will have to provide convincing, impactful and reliable unique information for such clinical applications to be appropriate, but the unmet clinical needs do exist! In our immediate future, we need to manage a broad array of issues in a proactive and diligent way. Other methodologies such as PET have gone through the same evolution and with appropriate awareness it can be managed initially on a site specific level and evolve then into a community/society based effort.

References and further literature are available upon request at: office@wcibmi.org

The Wright Center of Innovation in Biomedical Structural, Functional and Molecular Imaging has been established by a State of Ohio Third Frontier Program (PI Knopp) since 2003 and the contribution of the broad, interdisciplinary team is also gratefully acknowledged.