MR Safety Testing of Devices: How to Separate the Good from the Bad & the Ugly

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MR safety is an important topic for all users performing MR procedures on humans. Users have to judge with the help of the implant vendors and/or databases (like www.mrisafety.com or http://www.magresource.com/) if a patient/volunteer with an implant may undergo an MRI or not.
In this presentation, the main interest will be to give some inputs how to rate devices with respect to MR safety. The "rating" of a device with good, bad or ugly is more with respect to device testing and less with the outcome of the testing. A flexible device with long isolated wires (I would put it probably in the category ugly) will need a lot of testing efforts to be really sure that a label other than MR unsafe is appropriate. However, if a device was put in the category ugly, does not mean that it has to be MR unsafe. It may even behave, if appropriate designed, much better than other devices initially placed to the category bad.
There are different ASTM standards available which provide guidelines how to perform MR safety test: Force (ASTM F2052-06e1), Torque (ASTM F2213-06(2011)), RF heating (ASTM F2182-11a), and Artifacts (ASTM F2119–07). In addition a new standard (ISO/TS 10974:2012) has recently been published on testing active implants. This standard does also covers various interference effects of the MRI on active implant. In addition extended test methods for RF heating based on computer simulations have been included, which are not included in the ASTM standard.
Following the different standards helps to perform tests in a hopefully reliable and repeatable way.
But are limited testing enough for the given device? Testing a good implant will need less time compared with a bad or even ugly one. For example limited RF heating test of an ugly implant may not look that bad. However, changing configuration may dramatically change the behavior or if the device was well designed extensive tests may prove the limited heating.
Force and Torque can easily be tested. Knowing all used materials can gave already a first impression on the behavior in strong magnetic fields.
RF heating is much more demanding and even with a lot of experience; surprises (in both directions) are not avoidable. Devices containing no conductive material are certainly good and should show only limited RF heating. For all other implants the following parameters should be discussed to judge the potential effort of testing and partly also the likelihood of low RF heating results during testing:
Longest dimension, massive device vs. flexible one, not isolated vs. partly isolated vs. completely isolated (incl. thickness of isolation), device only partly in the body, inductive structures or capacitance which may change the behavior, sharp edges vs. smooth surface, long and thin vs. spherical, thin or thick structures etc.
Some of the parameters may (with enough experience) be used as a strong indication to predict low RF heating; others may serve as a first guess only.
For example a 1cm large Ti screw is very likely to behave nice with respect to RF heating (and also force), whereas for a 15 cm long and thin implant, it is rather unlikely that RF heating stays within 6°C for a 15min scan using a whole body SAR of 2W/kg. An example for an ugly implant could be a 50cm long sensor which enters the body only by a few cm and contains thin wires ending at the tip of the sensor. Such a device can in some configurations (more or less entered into the test liquid) show only limited heating, but after small changes in the test setup you may see RF heating far beyond any limits. To collect test data for such a device, extensive testing by changing several parameters may be needed before it could be labeled as MR conditional. However, if no special precaution has been taken during design of the device, it is also very likely that one test show high heating and the tests can be stopped with the conclusion: MR unsafe.
The learners should understand multiple parameters which help to separate the good medical devices (only with respect to MR safety testing) from bad and the ugly once. This will help those who design tests, but also users which have to check screening forms and look up safety info from devices.
If you find on the vendors webpage a device labeled to be fine for all MR scanners without any restrictions but you would put it to the ugly group, it could also be a strong indication that tests have not been performed as extensive as it would be needed for such an implant.