MR Safety Evaluations of Large External Fixation Frames and Clamps

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Introduction:
Two recently with respect to MR safety redesigned external fixation systems from Synthes (USA) have been evaluated in terms of MR safety aspects. External fixation systems are designed for management of fractures and lesions of the upper or lower extremities and pelvis. This fracture treatment concept may also be utilized to stabilize tibial osteotomies and to provide rigid support for knee or ankle joint arthrodeses. Open fractures, however, represent the major trauma application for external fixators because of the ability to properly manage soft tissue damage. Infection and vascular complications can be minimized while providing adequate fracture stabilization. MR examinations of patients with external fixation devices are not common, but polytraumatized patients with external fixation devices may be subjected to head, spinal, or other MR evaluations. Many of the metallic components of conventional external fixation devices are fabricated from feebly or highly magnetic materials. Thus, MR scans of patients with external fixation devices cannot be performed due to the possibility that torque, displacement or heating may be induced by large electromagnetic magnetic fields.

Methods:
Two assembled external fixation frames (Fig. 1) together with different components (five different clamps: 390.002, 390.003, 390.004, 390.007, 390.008; two types of schanz screws (steel / titanium); one carbon rod) of these new large external fixation systems (Ex Fix MR-safe, Synthes, Paoli, PA, USA) have been tested for force, torque, heating and artifact level. The force and torque measurements have been performed on an actively shielded whole body 3T Intera scanner (Philips Medical Systems, Best The Netherlands) according to ASTM F2052. All other measurements have been performed in a 1.5T Intera (Philips Medical Systems). For the heating measurements the frames have been placed in an 80x25cm^2 large tank. The screws were dipped ~6cm into 20l of a 0.45% saline solution. To reduce the thermal conductivity around the place of the measurements, the screws were placed in an agar phantom doped with 0.45% salt. Two fiber optic sensors of a Luxtron thermometer (Luxtron Corp., Santa Clara, CA, USA) were positioned next to the screw tip and a third sensor as a reference in the saline solution. Both frames were placed ~15 cm outside of the isocenter in right-left direction. Temperatures were measured during a 12 minutes long TSE sequence with a SAR-value of 3.8W/kg. The image artifacts arising from the clamps and the assembled frames have been evaluated according to ASTM F 2119.

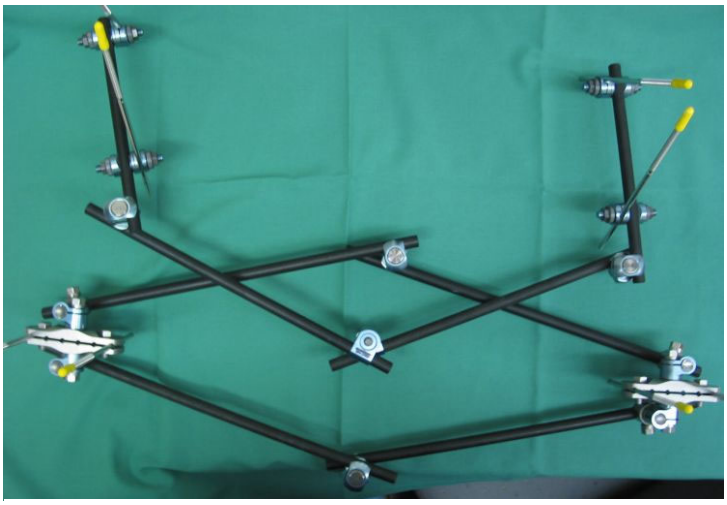

Figure 1: Two different frames were evaluated with respect to safety aspects in MRI. Upper frame is the pelvic frame; the lower one the diamond knee bridge frame (length 55cm).

Results:
The accelerations induced by force effects were in the range of 0.3-3.4ms^{-2} for the clamps, 0.2ms^{-2} for the carbon rod, 2.6ms^{-2} for the stainless steel screws and 0.3ms^{-2} for the titanium screws. No torque effects could be sensed by turning the clamps, rod or screws within the isocenter of the 3T MR unit, therefore no quantitative torque measurements have been performed. The pelvic frame showed a temperature increase of 1.2°C next to the screws and the knee bridge a temperature increase of 4.1°C. Normalizing the temperatures to a SAR-value of 2 W/kg, as recommended in ASTM F2182-02, the temperature increases will be reduced to 0.7°C for the pelvic frame respectively 2.1°C for the knee bridge. While the clamps produced in the images of the gradient and the spin echo sequence artifacts with a diameter of up to twice the size of the clamp, only minor artifacts could be seen around the carbon rods. The artifacts around the 5mm thick stainless steel screws were up to 4cm in diameter, and less than 1cm for the 5mm thick titanium screws.

Discussion:
The investigated clamps and frames are safe concerning force and torque effects in MR units up to 3.0T. Heating effects could be seen for both frames at 1.5T. The knee frame showed with up to 4°C (normalized 2.1°C) reasonable heating. However the screw was placed in an agar phantom with reduced thermal conductivity compared to perfused tissue, which provokes higher heating. In the normal operating mode of the body coil (SAR<2W/kg), the heating stays within the IEC-60601 limits, specified for extremities. The pelvic frame was within the limit up to the first level controlled mode. Images near or through the screws show artifacts, whereas the effects from the clamps may be less severe, since they are typically several centimeters away from the skin, outside of the body. The influence of the frames on the risk of peripheral nerve stimulation has not been investigated. However, due to the low resistance (~800Ω) between any two screws, additional currents may be induced within the frame, increasing the potential risk of peripheral nerve stimulation near the screws.

Conclusion:
Granted that the frames stay outside the body coil during scanning the tested new external fixation systems by Synthes are considered to be safe. However, if the frames lay inside the body coil of the MR system, the temperature increase near the screws may reach (in worst case situations) the limits mentioned in IEC 60601. Therefore, we recommend to reduce the SAR level below 2W/kg in order to avoid any potential risk.

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