Evaluation of the Forces Acting on a Highly Ferromagnetic Orthopaedic Implant at 1.5T and 3T

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INTRODUCTION: Orthopaedic implants are used to stabilise segments of the spine following fractures or degenerative disease, and are generally considered to be safe in the MR environment as they are firmly fixed in bone. The only orthopaedic implant which has been recorded to date as showing a substantial ferromagnetic response is the Perfix interference screw (Instrument Makar, Okemos, MI) [1]. An orthopaedic implant called the Posterior Fixator (Anatomica AB, Gothenberg, Sweden), which has not been previously recorded in the literature, was found to show a highly ferromagnetic response when brought into contact with a hand-held magnet. The purpose of this study was to measure and evaluate the translational and rotational forces acting on the Posterior Fixator in 1.5T and 3T MR systems.

METHODS: Translational force was measured using the method recommended by the American Society for Testing and Materials (ASTM) [2], which involved suspending the implant from a nylon thread at the point of maximum static magnetic field gradient, and measuring the angle of deflection using a protractor. A deflection angle of less than 45^o is considered to present no greater risk to a patient than normal daily activities in Earth's gravitational field. In the cases where the deflection was very large, small lead weights were attached to the implant to reduce the deflection angle so that the magnitude of the translational force could be calculated. Rotational force, or torque, was measured using both a qualitative and a quantitative method. The qualitative method involved positioning the implant at various angles on top of a paper protractor in the region within the bore of the magnet where the static magnetic field strength is uniform and maximal, and noting if any movement occurred. The torque was assigned a value using a previously published scale of 0 (no torque) to 4 (very strong torque) [3]. A device to allow quantitative measurement of torque was constructed using the guidelines provided by the ASTM [4], which allowed the torque acting on the implant to be calculated directly from the angle through which a set of torsion springs was compressed. This value can be compared to the torque due to gravity, which is calculated as the product of the longest dimension of the implant and its weight. Measurements were taken for each component of the implant individually, and with the implant assembled into a configuration which may be used in the treatment of a patient. All measurements were taken on a 1.5T system (Signa Excite, GE) and a 3T system (Signa HD, GE).

RESULTS: The results of the study are summarised in the following table:

Implant Component	Translational Force (deflection / N)		Torque (0-4 / Nmm)		
	1.5T	3T	1.5T	3T	Gravity
Expansion screw (5mm x 60mm)	$>45^o$ / 0.99 $\pm$ 0.017	90^o / 2.12 $\pm$ 1.06	4 / 18.1 $\pm$ 2.2	4 / 55.5 $\pm$ 5.7	4.7
Expansion screw (6mm x 55mm)	$>45^o$ / 1.00 $\pm$ 0.018	90^o / 2.13 $\pm$ 1.07	4 / 18.1 $\pm$ 2.2	4 / 55.5 $\pm$ 5.7	5.1
Spindle bolt	$>45^o$ / 2.97 $\pm$ 0.070	90^o / 5.87 $\pm$ 2.93	4 / 32.3 $\pm$ 3.5	4 / 91.8 $\pm$ 9.2	27.6
Fixation block	4^o / 0.004 $\pm$ 0.001	14^o / 0.015 $\pm$ 0.01	0 / 0	0 / 0	1.1
Combined implant	$>45^o$ / 5.13 $\pm$ 0.114	90^o / 9.15 $\pm$ 4.58	2 / 11.6 $\pm$ 1.7	2 / 29.7 $\pm$ 3.2	59.6

Based on deflection angle criteria, the translational force acting on the implant would be considered unsafe in both 1.5T and 3T MR systems. However, when the holding strength of a cortical screw securely fixed into bone is taken into consideration, which is 2500N for a standard 4.5mm screw fixed to a single cortex [5], the possibility of implant migration is considered to be unlikely. The torques acting on the spindle bolt and expansion screws individually are greater than the corresponding torques due to gravity in both the 1.5T and 3T systems, and hence would be considered to present a risk to patient safety. However, when the Posterior Fixator is assembled, the expansion screws are attached at an angle of 90^o to the spindle bolt, and the counterbalancing effect of this configuration results in a net torque which is less than the corresponding torque due to gravity. The analysis conducted during this study assumes that the Posterior Fixator is correctly assembled and securely fixed into bone, and it is likely that the risk to patient safety due to magnetic translational and rotational forces will increase, for example, in the event of implant failure or if the strength of the bone is particularly low.

CONCLUSIONS: While the individual components of the Posterior Fixator are subject to very large translational and rotational forces, which are many times greater than for any orthopaedic implant previously recorded, comparison with the relevant ASTM guidelines and consideration of the rigid fixation of the implant appears to show that the risk to patient safety under normal circumstances due to translational and rotational forces is less than the risk imposed by normal daily activities in Earth's gravitational field. However, it should be noted that this is a purely theoretical conclusion, and no clinical evidence currently exists to support this.

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