

Compatibility of magnetic resonance imaging in patients with orthopedic implants: manufacturer questionnaires

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ABSTRACT

In clinical practice, surgeons have stated that magnetic resonance imaging (MRI) can be performed in patients with titanium alloy implants. However, manufacturers and distributors of many implants may not comply with this common practice. As such, this study aimed to investigate manufacturers' views on MRI use in patients fitted with their implants.

The questionnaire survey was conducted between May and August 2018.

Is your product compatible with MRI? () Select from (1) to (3).

In case of (1) or (2), up to () Tesla.

(1) MRI can be performed even at the sites of implanted fixators.

(2) MRI can be performed at sites without implanted fixators.

(3) MRI cannot be performed, or the manufacturer does not approve MRI use (cannot issue a certificate).

The questionnaire forms were sent to 12 manufacturers, and the response rate was 100%. Manufacturers responded that they could not publicly allow MRI use in patients with their products.

These findings do not conclude that MRI cannot be performed in such patients. This survey revealed that currently decisions regarding MRI use is left to the treating physicians. This situation poses a great problem for medical safety and imposes a substantial burden on physicians. As many problems remain in the field of orthopedic surgery, manufacturers of implants should proactively manage issues surrounding the usage of MRI.

Keywords: magnetic resonance imaging, implant, total arthroplasty, fracture, patient safety

Abbreviations:

MRI: magnetic resonance imaging

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INTRODUCTION

With advances in medical technology, magnetic resonance imaging (MRI) has recently become essential in clinical settings. In the field of orthopedic surgery, MRI allows assessment of bones, soft tissues, and nerves, and it is a diagnostic imaging alternative to arthrography and

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myelography. Although MRI is a useful modality that does not result in exposure to radiation, there are problems with cost and safety.¹⁻³ MRI has been known to cause problems such as burn injuries, pain, and tinnitus. Instances of burn injuries have been reported in patients with implants, including pulse oximetry and Swan-Ganz thermodilution catheter devices.^{4,5} In addition, artifacts can also be a problem.^{1,2} However, as indicated by the advent of new cardiac pacemaker models, compatible with MRI examinations, technological innovation has driven the progress of implants.⁶⁻⁸ In the field of orthopedic surgery, many implants are now made of titanium alloy and considered to be compatible with MRI. The use of implants by orthopedic surgeons has been studied; however, many studies use MRI at field strengths up to 1.5 T only.^{3,9-11}

In actual clinical practice, surgeons have stated that MRI can be performed in patients with titanium alloy implants. However, only a few models, such as the Hoffmann III external fixation system (Stryker, Kalamazoo, MI), are sold specifically as MRI-compatible models, whereas the intentions of the majority of manufacturers and distributors of many implants remain unknown. Thus, this study aimed to investigate manufacturers' views on MRI use in patients with their implants.

MATERIALS AND METHODS

A questionnaire survey was conducted for manufacturers distributing locking plates for distal radius fractures, nails for trochanteric fractures, and joint prostheses for the knees and hips between May and August 2018. As for products manufactured overseas and imported to Japan, the survey was conducted on foreign manufacturers through their Japanese branches or importers of their products. We chose major implant companies who conducted more than 75% of the research share on each implant in our country. We have no conflict of interest to declare. The contents of the questionnaire survey were as follows:

Views of manufacturers on MRI compatibility in patients with their implants

Is your product compatible with MRI? () Select from (1) to (3).

In case of (1) or (2), up to () Tesla.

- (1) MRI can be performed even at the sites of implanted fixators.
- (2) MRI can be performed at sites without implanted fixators.
- (3) MRI cannot be performed, or the manufacturer does not approve MRI use (cannot issue a certificate).

RESULTS

The questionnaire survey was conducted from May to August 2018. The questionnaire forms were sent to 12 manufacturers, and the response rate was 100%. The following manufacturers were surveyed (manufacturer/Japanese distributors):

Acumed (U.S.A.) / Japan Medicalnext
DePuy Synthes, Johnson & Johnson
Kyocera
Medartis (Switzerland) / ME system
Meira
Mizuho
Next OrthoSurgical (U.S.A.) / NextMed International

Questionnaires about MRI for implants

Ortho Development Corporation (U.S.A.) / Japan Medical Dynamic Marketing
 Smith & Nephew
 Stryker
 Teijin Nakashima Medical
 Zimmer Biomet

Zimmer Biomet provided a list of its MRI-compatible products and the following comment instead of responding to the question on the survey:

“We have not evaluated our products that are not included in the table on the previous page (including plates for distal radius fractures, fixators for femoral fractures, and joint prostheses, which are targeted in this survey). Thus, we cannot vouch for the safety and compatibility of them.”

All other responding manufacturers selected option (3). In other words, they not state that their devices are compatible with MRI. The tables show responses according to types of implants (Table 1–4).

Table 1 Implants for distal radius fractures

COMPANY	IMPLANT	ANSWER	
Acumed (U.S.A.) /Japan Medicalnext	Acu-Loc 2 Wrist Plating System	3	
DePuy Synthes , Johnson & Johnson	2.4mm LCP Distal Radius Plate	3	
Medartis(Switzerland) / ME system	APTUS2.5	3	
Meira	DualLoc Radii system / Distal Radius Plate System	3	Japan only
Mizuho	Hearty Plate	3	Japan only
Next OrthoSurgical (U.S.A.) / NextMed International	GlobalForm VDR Fixation System	3	Japan only
Ortho Development Corporation (U.S.A.) / Japan Medical Dynamic Marketing	MODE Distal Radius Plate System	3	Japan only
Stryker	VariAx 2 Distal Radius	3	
Teijin Nakashima Medical	Locking Volar Plate System	3	Japan only

Table 2 Implants for trochanteric fractures

COMPANY	IMPLANT	ANSWER	
DePuy Synthes , Johnson & Johnson	TFN-ADVANCED / PFNA	3	
ME system	TURIUS Femoral Nail System	3	Japan only
Meira	Hook Pin Nail	3	Japan only
Mizuho	CHY II Nail	3	Japan only
Next OrthoSurgical (U.S.A.) / NextMed International	Multi-Fix Femoral Nail	3	Japan only
Smith & Nephew	Trigen intertan	3	
Stryker	Gamma3	3	
Teijin Nakashima Medical	Inter Blade Nail	3	Japan only

Table 3 Implants for total hip arthroplasty

COMPANY	IMPLANT	ANSWER
DePuy Synthes , Johnson & Johnson	CORAIL Hip System / ACTIS Total Hip System etc.	3
Kyocera	Initia Total Hip System	3 Japan only
Mizuho	MX HIP SYSTEM	3 Japan only
Next OrthoSurgical (U.S.A.) / NextMed International	NexFlex Bipolar System	3 Japan only
Ortho Development Corporation (U.S.A.) / Japan Medical Dynamic Marketing	Ovation Hip System/ Escaled Hip System	3 Japan only
Smith & Nephew	POLARSTEM / SL-PLUS MIA	3
Stryker	Accolade II / Exeter	3
Teijin Nakashima Medical	Preserve stem	3 Japan only

Table 4 Implants for total knee arthroplasty

COMPANY	IMPLANT	ANSWER
DePuy Synthes , Johnson & Johnson	ATTUNE Knee System	3
Kyocera	Kyocera Modular Limb Salvage System	3 Japan only
Ortho Development Corporation (U.S.A.) / Japan Medical Dynamic Marketing	Balanced Knee System	3 Japan only
Smith & Nephew	JOURNEY II	3
Stryker	Triathlon Total Knee System	3
Teijin Nakashima Medical	FINE Total Knee System	3 Japan only

DISCUSSION

Due to a rapid increase in the mean lifespan of the Japanese population, recent medical advances, and a very low birthrate, the ratio of older adults to the total population is rising. Under these circumstances, MRI is used for diagnosing a wide range of diseases and disorders. As cases requiring emergency MRI due to cerebrovascular accidents and other disorders increase,^{12,13} physicians on the scene are placed in a situation in which they must immediately decide whether MRI can be performed, even though there are many other technologies available to assess brain and other areas.¹⁴ Patients with cardiac pacemakers use a pacemaker diary, which indicates whether the device is compatible with MRI or not, thus facilitating these decisions. In contrast, orthopedic implants do not have the same associated information, and physicians do not know which device has been used without contacting the hospital where the implantation was performed.⁶⁻⁸ However, many orthopedic implants are now made of titanium, therefore, MRI presumably causes no major problems. Thus, MRI is currently performed at the discretion of physicians in clinical practice.

Plates used for the co-aptation of bone fragments are typically removed in some countries, including Japan; however, other countries, such as the United States, do not remove them. Differences depending on healthcare systems and cultures have also been reported.¹⁵ Even among orthopedic co-aptation devices used in Japan, plates are often removed for those implanted in patients with distal radius fractures, but femoral trochanter nails are rarely removed. Furthermore, once joint prostheses are implanted, they are left in the body permanently. These devices are only removed if problems such as infection develop. Given these circumstances, we believe that guidelines regarding MRI usage in patients with orthopedic implants left in the body for long

periods of time are required.

This study has several limitations. First, it is based on a questionnaire survey that did not include all implant manufacturers. Second, this study did not include manufacturers that are currently dealing with this issue or have no plan to do so. Third, the targeted implant types were limited.

CONCLUSION

In this questionnaire survey, manufacturers responded that they could not publicly endorse MRI use in patients with their products. These findings however do not conclude that MRI cannot be performed in such patients. In fact, MRI is frequently performed in orthopedic patients in clinical practice.¹⁶ In other words, this survey revealed the current situation in which decisions regarding MRI use is left to physicians on the scene. This situation poses problem with regards to medical safety and imposes substantial burden on physicians. As there are still many problems regarding the field of orthopedic surgery, it is hoped that manufacturers of implants will proactively deal with this MRI issue.

CONFLICT OF INTEREST

We have no conflict of interest to declare.

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