MRI Safety Information

Applicability

This MRI Safety Information is applicable to ROOTT Dental Implant System devices produced by TRATE: dental implants, dental abutments and healing abutments, made of:

- Ti (Commercially Pure Titanium Grade 4 according to ASTM F67 and ISO 5832-2) and Ti Alloy (Ti 6-Al 4-V ELI according to ASTM F136 and ISO 5832-3) which are considered paramagnetic and therefore weakly interact with magnetic fields,

Overview

Magnetic resonance imaging (MRI) is widely used for the diagnosis, staging, and follow-up of diseases. It uses magnetic fields and radio waves to generate images of the body. Because MRI devices use strong magnets, metal implants can pose a specific risk of potential migration of implants and radiofrequency (RF) induced torque and heating of the implants, which may cause damage to the surrounding tissue. The issues that exist for magnetically-activated dental implants also include possible demagnetization of the magnetic components and the substantial artifacts that the magnetic parts produce on MR imaging.

It is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field, additional displacement force measurements are considered unnecessary. A MR scanner's static magnetic field produces a torque (this parameter directly depends on the displacement force) on an object that acts to align the long-axis of the object with the magnetic field, just as a compass needle aligns itself with the earth's magnetic field (ASTM F2213-06).

The radiation frequency (RF) excitation pulses applied during an MR scan induce currents in the body which heat the body (ASTM F2182-11e). The specific absorption rate (SAR), measured in watts per kilogram (W/kg), is defined as the rate at which RF energy is deposited in tissue. MRI-related heating does not appear to pose problems to dental devices[1]. Studies[2] have shown that implants firmly fixed to the bone are not affected by the MRI-induced displacement forces and torque and revealed that the temperature change is negligible, indicating that concerns about tissue damage from RF heating are unfounded.

The emergence of image artefacts is expected and should be considered when necessary the analysis of images (ASTM F2119-07). Image artefacts pose no risk to the patient. In the analysis of the images the healthcare professionals will verify and circumvent the possibly distorted images[3].

Evaluation of dental implant configuration (RF Heating and Artifacts)

The evaluation of the worst-case device resulted[4] in the following device configuration of ROOTT R dental implant and two dental abutments (total weight of the full configuration is 1,54 g).

During the non-clinical worst-case study were evaluated the MR Image Artifacts in the Magnetic Resonance Environment of a 3 Tesla MR scanner according to ASTM F2119-07 (2013) and radio frequency field (RF-field) induced Heating during radio frequency application with a 128 MHz (3 Tesla equivalent) RF laboratory system according to ASTM F2182-19e2.

Summary of the MR safety testing:

- **MRI related (RF) heating**

For the metallic components of the ROOTT Dental Implant System the maximum temperature rise detected for the test object has been 6,5 ℃ at 3 T (exposed in this test within the 128 MHz

RF-laboratory system which is equivalent to 3 Tesla MR-system) after 15 min continuous scanning of sequence. It were reached in MR system reported whole body averaged specific absorption rate (SAR) of 3,5 W/kg of scanning (i.e., per pulse sequence) in the Normal Operating Mode[5].

The temperature rise of this RF heating testing performed in accordance to ASTM F2182-19e2 is under consideration of a static phantom without cooling processes like for example blood flow.

- **Image Artifacts in MR system**

Image Artifacts are not considered as primary safety issue, but additional information about MR image artifacts help clinicians to make a decision about the appropriateness of a given MR scan for a patient with an implant that is placed in the bore of the scanner during the scan.

In a 3 T MRI system, considered the maximum (worst-case) artifacts[5]:

- The worst artifact for the used SE sequence were for the test object height (object axis perpendicular to the main magnetic field B_0, reached 717% distortion relative to the actual test object heigh, maximum artifact is 19,7±4,2 mm.
- The worst artifact for the used GRE sequence were for the test object height (object axis vertical to the main magnetic field B_0, reached 700% distortion relative to the actual test object heigh, maximum artifact is 19,3±4,1 mm.

Conclusion

Non-clinical worst-case MRI testing was performed to evaluate the metallic ROOTT Dental Implant System devices in the MRI environment. Patient with ROOTT Dental Implants and corresponding Implant Abutments can be safely scanned in an MR system under the following conditions[6]:

- Nominal field strength of 3 Tesla (or equivalent operating frequency of 128 MHz);
- Recommended maximum MR System reported whole body averaged specific absorption rate (SAR) of 2,0 W/kg (Normal Operating Mode). Maximum MR system reported whole body averaged specific absorption rate (SAR) of 3,5 W/kg of scanning (i.e., per pulse sequence) in the Normal Operating Mode showed a maximum temperature increase of 6,5 ℃ in implants from the ROOTT Dental Implant System after 15 minutes of continuous scanning.
  SAR should be kept as low as possible for medical diagnosis in order to minimise any risks for the patient. The temperature rise is under consideration of a static phantom without cooling processes like for example blood flow.

The image artifact caused by the ROOTT dental implant and abutment may extend maximum up to 19,7±4,2 mm (SE) or 19,3±4,1 mm (GRE) from the devices when imaged at 3 T MR system.

ROOTT Dental implants are fabricated from a material that can be affected by exposure to MRI energy and is MR Conditional. The emergence of image artefacts is expected and should be considered when necessary the analysis of images. Image artefacts pose no risk to the patient.

Denture and crowns can be fabricated from a metal material which can be affected by MRI energy. Patient shall be informed. Removable restorations should be taken out prior to scanning.

Disclaimer

Due to the large variety of MRI scanners available on the market, TRATE cannot make any predictions regarding the safety or behaviour of our implants and components in any specific MRI system.

Finally, TRATE cannot take any responsibility for the composition and behaviour of any third party product (including crown, bridge, bar, denture, etc.), which is not distributed by TRATE and may contain materials which may not be compatible with MRI imaging.

Validity

Upon publication of these instructions for use, all previous versions are superseded.

Please note

For the purpose of legibility, TRATE does not use ™ or ® in the text. This does not affect TRATE's rights with regards to registered trademarks.

Change history

Ver	Date	Change description	Approval
01	2022-03-01	Printing date	V. Shulezhko
02	2022-07-11	PEEK has been removed from Section 1	V. Shulezhko

References

1. Shellock FG. Guidelines for the Management of the Post-Operative (Post-Op) Patient Referred for an MRI Examination. 2021. Available online: http://www.ismrm.org/smrt/safety_page/2021.Shellock.Guidelines-for-the-PostOp.Pt.pdf; and http://www.mrisafety.com/
2. Kim YH, Choi M, Kim JW. Are titanium implants actually safe for magnetic resonance imaging examinations? Arch Plast Surg. 2019; 46(1):96-97. doi:10.5999/aps.2018.01466
3. Woods OT. Standards for Medical Device in MRI: Present and Future. J Magn Reson Imaging. 2007; 26:1186-1189. DOI 10.1002/jmri.21140
4. Annex 6.17.2.1. Worst case analysis for MRI safety tests
5. Annex 6.17.1.1. MRI safety test protocols and reports
6. Annex 6.17.2.2. MRI safety evaluation