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RESEARCH ARTICLE

# Experience with magnetic resonance imaging of human subjects with passive implants and tattoos at 7 T: a retrospective study

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**Abstract**
*Object* Over the last decade, the number of clinical MRI studies at 7 T has increased dramatically. Since only limited information about the safety of implants/tattoos is available at 7 T, many centers either conservatively exclude all subjects with implants/tattoos or have started to perform dedicated tests for selected implants. This work presents our experience in imaging volunteers with implants/tattoos at 7 T over the last seven and a half years.
*Materials and methods* 1796 questionnaires were analyzed retrospectively to identify subjects with implants/tattoos imaged at 7 T. For a total of 230 subjects, the type of local transmit/receive RF coil used for examination, imaging sequences, acquisition time, and the type of implants/tattoos and their location with respect to the field of view were documented. These subjects had undergone examination after careful consideration by an internal safety panel consisting of three experts in MR safety and physics.
*Results* None of the subjects reported sensations of heat or force before, during, or after the examination. None expressed any discomfort related to implants/tattoos. Artifacts were reported in 52 % of subjects with dental implants; all artifacts were restricted to the mouth area and did not affect image quality in the brain parenchyma.
*Conclusion* Our initial experience at 7 T indicates that a strict rejection of subjects with tattoos and/or implants is not justified. Imaging can be conditionally performed in carefully selected subjects after collection of substantial safety information and evaluation of the detailed exposure scenario (RF coil/type and position of implant). Among the assessed subjects with tattoos, no side effects from the exposure to 7 T MRI were reported.

**Keywords** MR safety · 7 T · MRI · Implants · Tattoos · Ultra-high-field · UHF

## Introduction

Magnetic resonance imaging (MRI) is a non-invasive imaging technique that was introduced into clinical diagnostics in the 1980s. Since then, MRI has proven to be the imaging modality of choice for a variety of diseases as expressed by more than 30,000 installations worldwide and over 70 million examinations per year [1]. Although most of the MR systems around the world operate at 1.5 Tesla (T) or 3 T, the number of installations of 7 T MR systems has increased very rapidly over the last 10 years [2]. The rise of 7 T MR systems has led to promising results obtained for both anatomical and functional imaging studies [3–6].

Furthermore, with the increasing number of clinically-oriented MRI studies at 7 T, the examination of patients with implants has become relevant. Also, artistic tattoos and permanent make-up have become mainstream and are increasingly encountered in both patients and healthy

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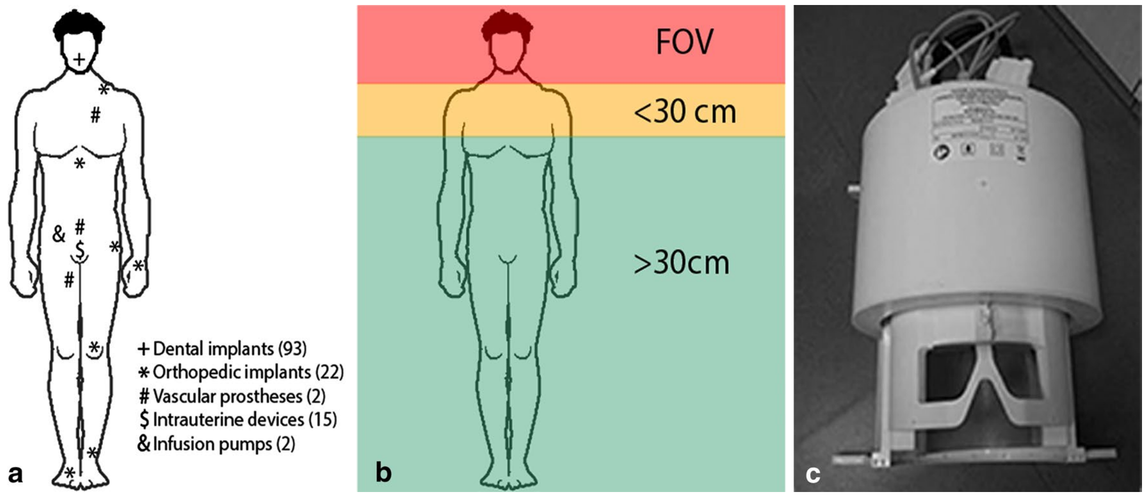


**Fig. 1** **a** Distribution of a number of implants imaged at 7 T. **b** Location of implants and tattoos with respect to head scans. The *red* area represents the exposure volume of the transmit coil. The *orange* part shows locations of tattoos or implants less than 30 cm from the exposure volume of the transmit coil. **c** Circularly polarised (CP) birdcage transmit coil with a 32-channel receive array (Nova Medical, USA)

**Table 1** Overview of decision-making process for implants reported by subjects scheduled for 7 T MRI examinations

| Location of implant w.r.t. RF coil | Minimum requirement for decision-making | Rationale |
|---|---|---|
| >30 cm distance | Non-magnetic material (e.g., titanium)<br>MR conditional labeling for 3 T | Due to local transmit RF coil, interaction between (stray) RF field and implant may be neglected*, leaving attractive forces and gradient-induced heating as residual concerns |
| <30 cm distance | Additional knowledge about typical power deposition of RF coil at location of implant | Total exposure volume of local RF coil is typically larger than its physical dimension; potential interaction of stray field with implant should be investigated |
| Within direct RF exposure volume | Dedicated safety assessment at 7 T | Alteration of SAR distribution and increased maximum local SAR values cannot be excluded and need detailed investigation |

*Asterisk* However, implants more than 30 cm from the RF coil were not cleared for 7 T automatically as the bore of the 7 T magnet can act as a hollow circular waveguide [61], leading to potential RF interaction with distant implants. Implants with dimensions close to or larger than the resonance wavelength were conservatively excluded

*w.r.t.* with respect to, *RF* radio frequency, *SAR* specific absorption rate

volunteers to be included in MRI studies. However, as 7 T MRI is currently not medically indicated and as ultra high-field (UHF) MRI facilities tend to be rightly very cautious with respect to the higher resonance frequency and various transmit radiofrequency (RF) coil configurations, the general question of contraindications for a 7 T scan is regularly discussed. Within the UHF community, some sites conservatively exclude all subjects with tattoos or metallic implants regardless of type or location, while other sites have already performed dedicated safety tests for certain implants [7–11] or have included carefully selected subjects with implants or tattoos [12].

In general, performing an MR scan on patients with metallic implants at any field strength is contraindicated unless the implant manufacturer includes "MR Safe" or "MR Conditional" labeling for the specific implant in the instructions for use [13]. However, no standards or test methods currently explicitly address MR safety testing for implants at 7 T, although some standards describe the MR environment in general or imply a transfer of test methods to MR field strengths other than 1.5 and 3 T.

At a field strength of 7 T, some complex and specific challenges arise. The increase of the field strength leads to a reduction of the Larmor wavelength λ, which is roughly 14 cm at 7 T in the human body (example given for liver tissue with a permittivity of 53.6) [14], much less than the Larmor wavelength of 29 and 52 cm for 3 and 1.5 T, respectively. Incident RF electric fields induce currents on the metal surface of an implant which subsequently generate concentrated current densities inside the body tissue

**Table 2** Overview of the different transmit/receive RF coils used to acquire images from subjects with implants and/or tattoos

| Coil reference | Coil description |
|---|---|
| Siemens 7.0T TIM head coil, Invivo Corp., FL, USA | CP transmit/receive quadrature birdcage with an inside diameter of 26.5 cm and an outside diameter of 31.5 cm |
| NM-008A-7P and NMSC025-16-7P, Nova Medical, Wilmington, MA, USA | NM-008A-7P: Active detunable quadrature birdcage, inside diameter 29.2 cm, outside diameter 37.5 cm, and physical length 26 cm<br>NMSC025-16-7P: 32-channel receive phased array coupled with NM-008A-7P |
| P-H08L-070-00114, Rapid Biomed, Rimpar, Germany | This coil has 8 independent rectangular loop transmit/receive channels, inside diameter 23.5 cm, outside diameter 31 cm, and physical length 21 cm |
| Custom-built 8-channel transceiver meander stripline head coil [63] | The head coil consists of 8 elements (length 25 cm). The inner housing is octagonal with an inner diameter of 26 cm and an outside diameter of 31 cm |
| Custom-built 8-channel transceiver meander stripline body coil [49] | The body coil consists of 2 arrays with 4 elements each (length 25 cm) that are placed dorsally and ventrally on the human body |
| Siemens 7.0 T Extremity, Invivo Corp., FL, USA | CP transmit/receive quadrature birdcage with an inside diameter of 18 cm and an outside diameter of 25.5 cm |

Please note that the radiated power is relatively high for conventional stripline elements. The use of meanders significantly decreases field propagation [62]

*CP* circularly polarised

at the ends and edges of the implant, leading to an elevation of the specific absorption rate (SAR) and potential temperature rise. Hence, the short wavelength at 7 T not only introduces strong inhomogeneities in MR images due to $B_1$ artifacts, but can also lead to strong coupling (high current densities) between the electromagnetic field and conducting implants. The reduced RF wavelength at 7 T in human tissue (generally in the range of 10–15 cm) can produce resonance effects in implanted medical devices of shorter dimensions compared to 1.5 or 3 T. In a study at 1.5 T on RF-induced temperature elevations on metallic wires, Armenean et al. [15] showed that heating peaks occur between classical resonant lengths at multiples of λ/4 for the implant. Furthermore, heating not only occurs at the tip, but also along the implant. Hence, avoiding classical resonant lengths (λ/2, or λ) is not sufficient to ensure patient safety. Besides the antenna effect of implants with a certain length or circumference, any metallic structure distorts the incident electromagnetic field, which may lead to changes in the SAR (and temperature) distribution, particularly for UHF imaging where the coupling of the electromagnetic field to the human body and to implants becomes more complex [16, 17]. Implants with small linear dimensions relative to the wavelength can be expected to have only minimal impact on the local SAR. Nevertheless, Winter et al. [18] found an increase in the local 1-g SAR of roughly 50 % for stent-like structures with a length of 1 cm at 7 T, with a lower impact on the local 10-g SAR.

Furthermore, only local transmit RF coils of various designs and specifications are used at 7 T, whereas nearly all MR scans at clinical field strength are performed with integrated whole-body RF transmit coils. This aspect is particularly important in high-field MRI, since field distribution and polarization are significantly non-uniform in the human body and, moreover, depend on the design of the local transmit coil and the size and tissue distribution of the body [19]. Of course, also other features of UHF MRI need to be considered when discussing MR safety, such as travelling wave effects and altered field distribution and polarization when using parallel transmission techniques (RF shimming, Transmit SENSE) [20, 21], which can have a substantial impact on SAR [22].

Whether in clinical settings or at research sites, dental implants are the most common implants seen. Dental implants are generally of no concern at clinical field strength [23], but may be at 7 T, especially since intracranial imaging is one of the most frequently performed applications at 7 T. One of the major concerns of scanning dental implants at clinical field strength is the induction of artifacts due to the presence of metal that may render imaging results useless [24–27].

In addition to dental implants, there are a wide variety of other metallic implants that might be encountered in subjects being considered for a 7 T MR examination. Also, patients and healthy volunteers with artistic tattoos and/or permanent make-up are more and more encountered in MRI studies. Since tattoos are a relative contraindication at clinical field strength [28], an active topic is whether a tattoo should be considered an absolute contraindication at 7 T or not [12]. Especially tattoos older than approximately 20 years, as well as body art not obtained in proper studios (e.g., among inmates),

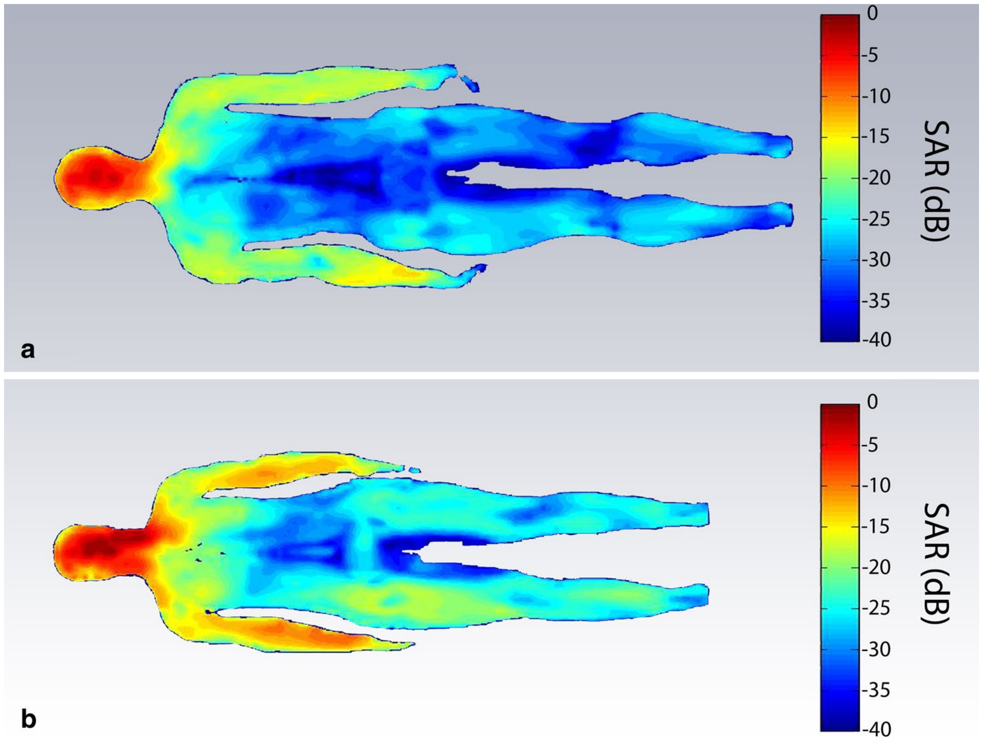


**Fig. 2** Distribution of the local 10 g-averaged SAR obtained with a finite-difference time-domain (FDTD) solver (SEMCAD-X, SPEAG, Zurich, Switzerland) for a custom-built meander stripline head coil [63] in heterogeneous body models of the 'Virtual Family' [42] (**a** Duke, **b** Ella). The total input power was scaled so that the local 10 g-averaged SAR reached the International Electrotechnical Commission (IEC) limit of 10 W/Kg [65]. Both **a** and **b** show a significant decrease of the local SAR at a distance of 30 cm from the transmit coil for both trunk (between 40- and 1000-times lower than the maximum value in the head) and arms (10- and 20-times lower than the maximum value in the head for the female and male model, respectively). In **b**, the local SAR is reduced by a factor greater than 100 in the pelvic region where intrauterine devices are located

are suspected to include iron oxide and other metals to a high degree [29, 30]. Among the millions of MR scans that have been performed since the advent of MRI, very few incidents at clinical field strengths related to tattoos or permanent make-up have been reported. Even if incidents with RF-induced skin burns [31–38] or skin irritations allegedly induced by torques and attractive forces on ferromagnetic ink particles [39, 40] have sporadically happened, there is a strong general history of safe use in imaging patients with tattoos up to 3 T [41]. Such history has not yet been established at 7 T. On the other hand, at 7 T, the majority of examinations are performed with local transmit RF coils, e.g., transmit head coils; thus, RF-induced skin burns in tattoos located outside the RF-exposed body areas are unlikely. The use of local transmit RF coils at 7 T can be seen here as advantageous for implants or tattoos that are at a sufficient distance from the exposure volume of the RF coil. This study presents 7.5 years of experience at our institute in imaging patients and healthy volunteers with implants and/or tattoos at 7 T.

## Materials and methods

Questionnaires and screening forms from October 2006 to April 2014 (7.5 years) were analyzed retrospectively to identify all subjects with implants and/or tattoos cleared for imaging at our institution. During this period, 230 out of 1796 healthy volunteers and volunteers with known pathologies had implants or tattoos and underwent an MR examination on a whole-body 7 T MR system (Magnetom 7 T, Siemens Healthcare, Germany). Of the 230 subjects, 109 presented with one or several tattoos and 135 reported one or several implants; 14 subjects had both tattoos and implants. For the 135 subjects with implants, 93 of them had their implant located in the orofacial region (dental implants), whereas the other implants were located elsewhere in the body (Fig. 1a).

All subjects were cleared for 7 T on a case by case basis by an MR safety expert panel in our institute, consisting of three physicists and engineers with extensive experience in MRI and RF effects. The types of implants (material, dimension, geometry) were carefully examined as well as their

**Table 3** Overview of 93 subjects with dental implants imaged at 7 T

| Type of dental implant | Number of subjects | Numbers of subjects with dental implants in the exposure volume of the transmit coil | Head coil used when implant in the exposure volume of the transmit coil: number of subjects | Number of subjects scanned at 1.5 or 3 T with implants in the exposure volume of the transmit coil |
|---|---|---|---|---|
| Dental braces | 12 | 7 | Nova medical 6 | 1 |
| | | | Custom-built 1 | |
| Retainers | 36 | 31 | Nova medical 25 | 5 |
| | | | Custom-built 3 | |
| | | | Rapid biomed 3 | |
| Dental bridges | 18 | 17 | Nova Medical 15 | 10 |
| | | | Custom-built 1 | |
| | | | Invivo 1 | |
| Crowns | 22 | 21 | Nova medical 17 | 7 |
| | | | Custom-built 4 | |
| Pivot teeth | 6 | 6 | Nova medical 5 | 4 |
| | | | Custom-built 1 | |

One subject presented with both bridges and crowns

location with respect to the exposure volume of the transmit coil of each study. The decision-making process was basically divided into three categories which are explained in Table 1. Here, a distance of 30 cm between an implant and the local RF coil was used to define the categories, as this distance yielded almost no stray RF fields at the location of the implant for the head coil (Fig. 1c and Table 2) and body coil used (Table 2). Numerical simulations (SEMCAD X SPEAG, Zurich, Switzerland) conducted with two heterogeneous body models (‘Duke’ and ‘Ella’) [42] confirm a significant decrease of the local SAR in the trunk beyond 30 cm, as shown in Fig. 2a, b. Furthermore, the SAR in the extremities, particularly in the arms, is also substantially lower (local SAR 10- and 20-times lower in the wrist than in the head for the female and male model, respectively). This behavior is substantially different to clinical routine (1.5 and 3 T using body coils) where the maximum local SAR is often located in peripheral extremities [43, 44]. Of course, in general, travelling wave effects need to be considered, especially for implants with dimensions near resonance or larger than a quarter of the wavelength, even when they are located a large distance from the transmit coil. These implants should be excluded without detailed simulations in which the full magnet bore, including the shield of the gradient coil, are included to confirm that the aforementioned rule of thumb remains valid for each individual exposure scenario. If applicable, information about the exact location of the reported implant was assessed from previous computer tomography (CT) or plain X-ray imaging retrieved from the picture archiving and communication system (PACS) of the referring hospital.

Regarding tattoos, tattoos located less than 30 cm from the RF coil or located within the RF coil were cleared for imaging if they were made after the year 2000 and in countries of the European Union as well as in proper tattoo studios. This limit was set based on a survey from Tope et al. [41], which showed that only 2 out of 135 subjects with tattoos experienced slight tingling or a sensation of burning associated with MRI. The rising popularity of tattoos in Europe has increased awareness of official bodies regarding the potential presence of toxic substances in the ink. As a result, two resolutions of the Council of Europe were ratified. The resolution ResAP (2003) 2 [45] published in 2003 lists substances that should not be included in tattoo ink. In 2008, the revised resolution ResAP (2008) 1 [46] superseded ResAP (2003) 2 and introduced maximum allowable concentrations of (metallic) impurities. Nevertheless, in Germany it can be assumed that almost all tattoo studios already started using approved ink approximately in the year 2000, as the Cosmetic Commission from the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung) recommended regulations for tattoo ink in this year [47].

Figure 1b shows the location of the implants and tattoos with respect to the exposure volume of a transmit head coil. For implants inside the exposure volume of the transmit coil, the acquired 7 T MR images were screened for the presence of artifacts. The impact of these artifacts was assessed qualitatively by visual inspection as to whether their disturbances were confined to the direct vicinity of the implants or if they impaired the depiction and

**Table 4** Overview of 22 subjects with orthopedic implants imaged at 7 T

| Type of implant | Number of volunteers | | Coil used when implant was in direct exposure volume of the transmit coil | Rationale for 7 T imaging |
|---|---|---|---|---|
| Biopolymer screw to support the anterior cruciate ligament (ACL) | 1 | | CP knee coil (Invivo Corp, Fl, USA) | Polymer screw was made of non-metallic and non-conductive material |
| Endobuttons (12 mm × 4 mm) made of titanium to support ACL | 1 | | CP knee coil (Invivo Corp, Fl, USA) | Dimensions of endobuttons were small with respect to RF wavelength; non-critical location |
| Total knee prosthesis (Legion Oxinium, Smith and Nephew, London, UK) | 1 | | – | MR conditional up to 3 T. Subjects with a plate in the clavicle and screws in the cervical vertebrae were imaged for the elbow and the knee, respectively. Other subjects received head scans. All implant locations were located more than 30 cm away from the RF coil. For head scans, Fig. 2 indicates a minimum decrease in SAR levels by a factor of 10 in the wrist. Figure 3 shows no significant increase of the SAR for the patient with a generic hip implant |
| Total hip prosthesis (ASR TM, DePuy, IN, USA) | 1 | | – | |
| Titanium osteosynthesis plates | Ankle | 2 | – | |
| | Clavicle | 1 | | |
| | Femur | 2 | | |
| Titanium screws | Cervical vertebrae | 1 | – | |
| | Wrist | 2 | | |
| | Hip joint | 2 | | |
| | Knee | 4 | | |
| | Ankle/feet | 6 | | |

One subject had a titanium screw in both his knee and his foot and another one had a titanium screw in both his hip and his foot

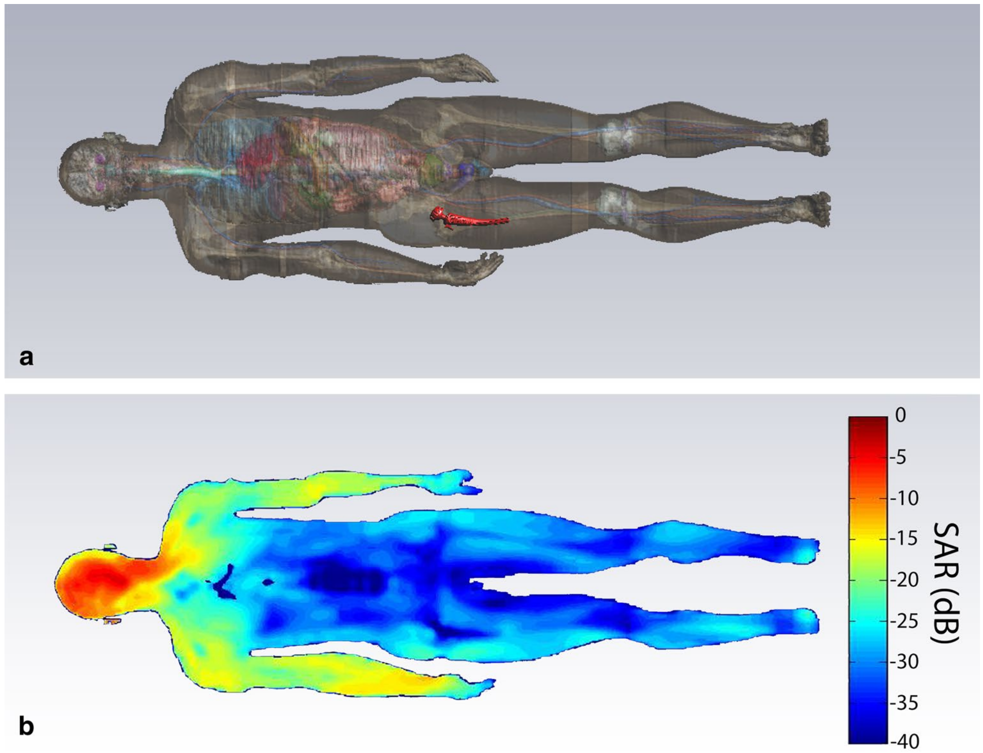


**Fig. 3** Exposure scenario used to determine potential SAR elevations near a generic hip implant during a head examination with a custom-built 8-channel transceiver meander stripline head coil [63]. The total input power was scaled so that the maximum local 10 g-averaged SAR, which is located in the head, reached the IEC limit of 10 W/kg [65]. **a** Heterogeneous male body model (Duke) with the generic implant at the right hip. **b** The 10 g-averaged SAR distribution. No significant SAR elevation occurred near the generic hip implant. SAR levels at the implant were at least 100 times lower compared to the SAR generated in the head region

delineation of the structure of interest. The different transmit/receive RF coils used to acquire images from subjects with implants and/or tattoos are listed in Table 2, and one of them is exemplarily shown in Fig. 1c.

## Dental implants

A total of 93 carefully selected volunteers underwent a 7 T head scan with a known dental implant. Details regarding the individual numbers and types of dental implants are provided in Table 3. Among these 93 subjects, 83 had their implants directly in the exposure volume of the transmit coil (head coil; CP, no parallel transmission techniques). Subjects with retainers were cleared for 7 T based on the work of Wezel et al. [10, 11], who found no substantial heating around retainer wires of up to 47 mm length when scanning within SAR guidelines for the head. Additionally, all implants were rather small with respect to the wavelength and located in or near non-critical tissue known to have many highly sensitive thermoreceptors. In all cases a magnetization-prepared rapid gradient-echo (MPRAGE) sequence was used with imaging parameters described by, e.g., Wrede et al. [48], while the remaining imaging protocol included other MRI sequences depending on the scope of the study such as time-of-flight (TOF), susceptibility weighted imaging (SWI), two dimensional (2D) and three dimensional (3D) echo planar imaging (EPI), fast low angle shot (FLASH), and turbo spin echo (TSE). The MPRAGE sequence applied approximately 45 % of the allowed SAR (head local SAR limit: 10 W/Kg) with an acquisition time of 6 min. In several cases, directly comparable imaging was performed at 1.5 or 3 T using a combined head/neck receive array coil (Siemens Healthcare, Erlangen, Germany). Table 3 summarizes the data of the subjects with dental implants.

## Other implants

A total of 42 subjects with miscellaneous implants underwent imaging: 22 subjects presented with orthopedic implants, 2 with vascular prostheses, 1 with an implanted port, 1 subject with surgical clips, 15 with intrauterine devices (IUD), and 2 with infusion pumps. One subject appeared with both an orthopedic implant and an intrauterine device. Details are summarized in Tables 4 and 5. MPRAGE was again the most common sequence used in the examinations, with other MRI sequences used depending on the scope of the study.

## Tattoos and permanent make-up

One hundred and eight (108) volunteers with one or multiple tattoos underwent 7 T imaging. One subject with permanent make-up at the eyebrows was cleared for imaging at 7 T. Of the 108 subjects with tattoos, 2 had them directly in the exposure volume of the transmit coil and 24 had them

**Table 5** Overview of miscellaneous implants imaged at 7 T

| Type of implant | Implant, number of volunteers | | Rationale for 7 T imaging |
|---|---|---|---|
| Intrauterine devices | Mirena (Bayer Healthcare, Germany)<br>NuvaRing (Merck and Co., USA)<br>Various copper uterine devices | 9<br>3<br>3 | All subjects underwent a head examination. At the location of intrauterine devices (IUDs), a decrease in SAR by a factor 100 compared to the head is shown in Fig. 2b. None of the IUDs contained ferromagnetic material. However, for the Mirena IUD, the retraction thread contains ferromagnetic oxide (length: 90 mm). In a study by Rauschenberger et al. [57], in 2011, only minor and uncritical deflection angles and heating at the retraction thread were observed at 7 T |
| Port | Titanium implantable port (Art. No. 607301, Bard Access Systems, USA) | 1 | MR conditional up to 3 T and implant location was more than 30 cm away from the RF coil (8-cha stripline body coil placed over pelvis region). Numerical simulations did not reveal any increase in the localized SAR for either CP + or CP2 + mode excitation under the given exposure scenario, as shown in Fig. 4. The subject was imaged at 3 T previously |
| Surgical clips | 7 clips (10 mm length) after partial lung resection | 1 | At least 15 cm distance between head coil (32-channel from Nova Medical) and first clip. Clips were well separated from each other, as shown in Fig. 5. Very low SAR values in the thorax are known from simulations in Fig. 2 and in [64]. The length of clips were much smaller than a quarter of the RF wavelength |
| Vascular prostheses | Stent in the femoral artery<br>Y-stent and a coronary stent | 1<br>1 | Both subjects underwent a head examination. Stents were made of non-ferromagnetic material (Nitinol), and both subjects were imaged at 1.5 T before being examined at 7 T. A coronal stent was placed 20 cm from the RF coil with a decrease in the SAR by a factor 100 and 40 compared to the head, as shown in Figs. 2a, b, respectively |
| Infusion pumps | MiniMed paradigm pump, Model MMT-512WWL, Medtronic, USA | 2 | The pump was removable and only the cannula and non-metallic Teflon needle remained in place |

None of these implants was within the exposure volume of the RF coil

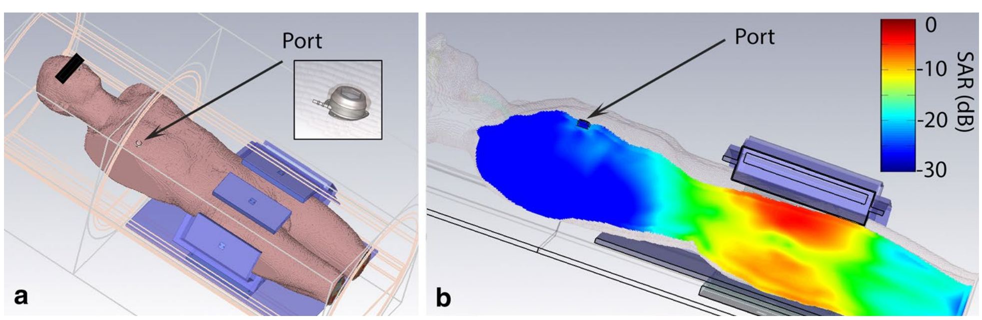


**Fig. 4** Exposure scenario used to determine potential SAR elevations near an implantable port when exciting with a custom-built 8-channel transceiver meander stripline body coil [49] placed around the pelvis of a heterogeneous male model (Duke). **b** Local SAR distribution (10 g-averaged) obtained with an FDTD numerical solver (CST Microwave Studio, CST GmbH, Germany) in a slice containing the implantable port. Although SAR elevations are present at the port, the local SAR values are a factor of 100 lower compared to the local SAR generated by the RF coil alone in the pelvic region

close to but not directly within the exposure volume; i.e. the tattoo was at the shoulder while the subject underwent a head exam. Eighty-two had their tattoos at least 30 cm away from the RF coil. All subjects were questioned regarding the origin of the tattoo and, if possible, regarding the composition of the ink. The two tattoos located directly in the exposure volume of the transmit coil were both at the lower part of the back and were imaged with a custom-built 8-channel transceiver stripline body coil [49]. Figure 6a shows one of the tattoos. For the 24 tattoos located less than

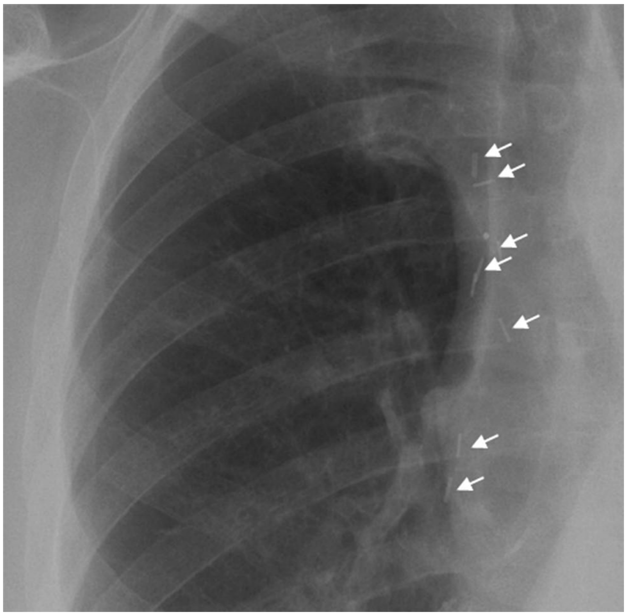

**Fig. 5** X-ray image obtained in a subject (m, 58 years) scheduled for head imaging with seven clips present after partial lung resection. Each clip has a dimension of 10 mm and is positioned at least 15 cm from the exposure volume of the transmit coil. *Arrows* show the location of each clip

30 cm away from the exposure volume of the transmit coil, only head scans were performed. The orange part of Fig. 1b shows the location of these tattoos. Nine of these were located on the upper part of the back, 14 on the shoulder, and 1 on the upper part of the chest. All tattoos were drawn in Germany and one in Thailand, the largest having a maximum size of roughly 10 cm by 40 cm, as shown in Fig. 6b. Since the subject with the tattoo drawn in Thailand had been imaged at 1.5 and 3 T several times without any side effects, the subject was cleared for imaging at 7 T. Fig. 6c–e show three other examples of tattoos close to the exposure volume of the transmit coil. Eight subjects were scanned with an 8-channel head coil (P-H08L-070-00114, Rapid Biomed, Rimpar, Germany). Fifteen subjects were scanned with a birdcage transmit and 32-channel receive head coil (Nova Medical, Wilmington, MA, USA) The final two subjects were scanned with a quadrature birdcage head coil (Invivo Corp., Gainesville, FL, USA). One subject was scanned with both birdcage head coils (CP transmit/receive quadrature birdcage from Invivo Corp. and birdcage transmit head coil with 32-channel receive from Nova Medical).The subject with permanent make-up at the eyebrows underwent a liver examination using the custom-built 8-channel transceiver stripline body coil [49]. Although this subject was not cleared for a head scan at 7 T because of the known presence of high levels of iron oxide (typically between 7 and 25 %) in the pigment of the permanent make-up, clearance was given for the abdominal scan. All scans were performed using the described local transmit/receive RF coils. While all head scans were performed with standard circular polarization (CP+), static RF shimming was applied in examinations with the 8-channel meander stripline body coil.

## Results

None of the subjects reported sensations of heat or force during or after imaging, nor regarding discomfort related to the implants or tattoos. For the metallic implants located within the imaging volume, artifacts were clearly visible in the 7 T images, but these remained restricted to the direct


**Fig. 6** **a** Tattoo located at the lower part of the back, drawn in Germany in 2003 and composed of black and blue ink. It was directly in the exposure volume of the transmit coil and imaged with a custom-built 8-channel transmit/receive meander stripline body coil. **b**–**e** Four examples of tattoos close to the examination exposure volume of the transmit coil (*orange* zone according to Fig. 1b). The tattoo shown in **b** was drawn in Germany and had a width of approx. 25 cm. Tattoos shown in **c**–**e** were drawn in Germany. Examinations were performed with head coils for the latter four tattoos

**Table 6** Overview of results obtained in this study

| Implant type | Implant subtype | Number of subjects | Number of subjects with an implant in the exposure volume of the transmit coil | Number of subjects with image artifacts |
|---|---|---|---|---|
| Dental implants | Dental braces | 12 | 7 | 6 |
| | Retainers | 36 | 31 | 12 |
| | Dental bridges | 18 | 17 | 9 |
| | Crowns | 22 | 21 | 13 |
| | Pivot teeth | 6 | 6 | 3 |
| Orthopaedic implants | Biopolymer screw | 1 | 1 | 0 |
| | Endobuttons | 1 | 1 | 1 |
| | Total knee prosthesis | 1 | 0 | 0 |
| | Total hip prosthesis | 1 | 0 | 0 |
| | Osteosynthesis plates | 5 | 0 | 0 |
| | Titanium screws | 15 | 0 | 0 |
| Other implants | Intrauterine devices | 15 | 0 | 0 |
| | Port | 1 | 0 | 0 |
| | Surgical clips | 1 | 0 | 0 |
| | Vascular prostheses | 2 | 0 | 0 |
| | Infusion pumps | 2 | 0 | 0 |
| Tattoos and permanent make-up | Tattoos | 108 | 2 | 0 |
| | Permanent make-up | 1 | 0 | 0 |

No subject reported a sensation of force or heat; note that the absence of heat sensation is not a reliable indicator in cases where the implant is located in anatomy lacking thermoreceptors

vicinity of the implants and did not affect image quality in the areas of interest. Table 6 gives an overview of the results obtained in this study.

### Dental implants

Example artifacts due to metallic dental implants close to the imaging area of interest are shown in Figs. 7 and 8.

### Other implants

Artifacts were clearly visible for one subject with two titanium endobuttons in the knee area, as shown in Fig. 9a. In Fig. 9b, the artifacts associated with the two endobuttons are clearly visible in a corresponding CT image. For the subject with a polymer screw, no artifacts close to the screw were visible and the implant was clearly identifiable, as shown in Fig. 9c.

### Tattoos

No reddening was visible in the region of the tattoos subsequent to imaging.

## Discussion

Since no dedicated safety tests for 7 T are recommended in current standards, careful attention was paid to obtain the fullest possible information about implants. Important for the decision-making process was the American Society for Testing and Materials (ASTM) classification which includes "MR Safe", "MR Conditional" and "MR Unsafe" labeling [13] based on four tests (force, torque, RF heating, and artifacts) [50–53]. Implants outside the exposure volume of the RF coil were required to have "MR Conditional" labeling at 1.5 or 3 T, as the gradient systems utilized at 7 T are similar in maximum gradient strength and slew rate compared to the gradients at lower field strengths. A conditionality regarding the SAR could be neglected if a sufficient distance between the RF exposure volume and implant was retained, as only local transmit RF coils were used at 7 T. Of course, implants were required to exhibit no significant forces or torques from the static magnetic field. Here, it may be noted that, due to lower gradients in the stray field, a passively shielded 7 T magnet yields similar forces compared to an actively shielded, state-of-the-art, short-bore 3 T magnet. Labeling information may, for example, be gained from specific websites [54, 55] or directly from the website of the implant manufacturer. In

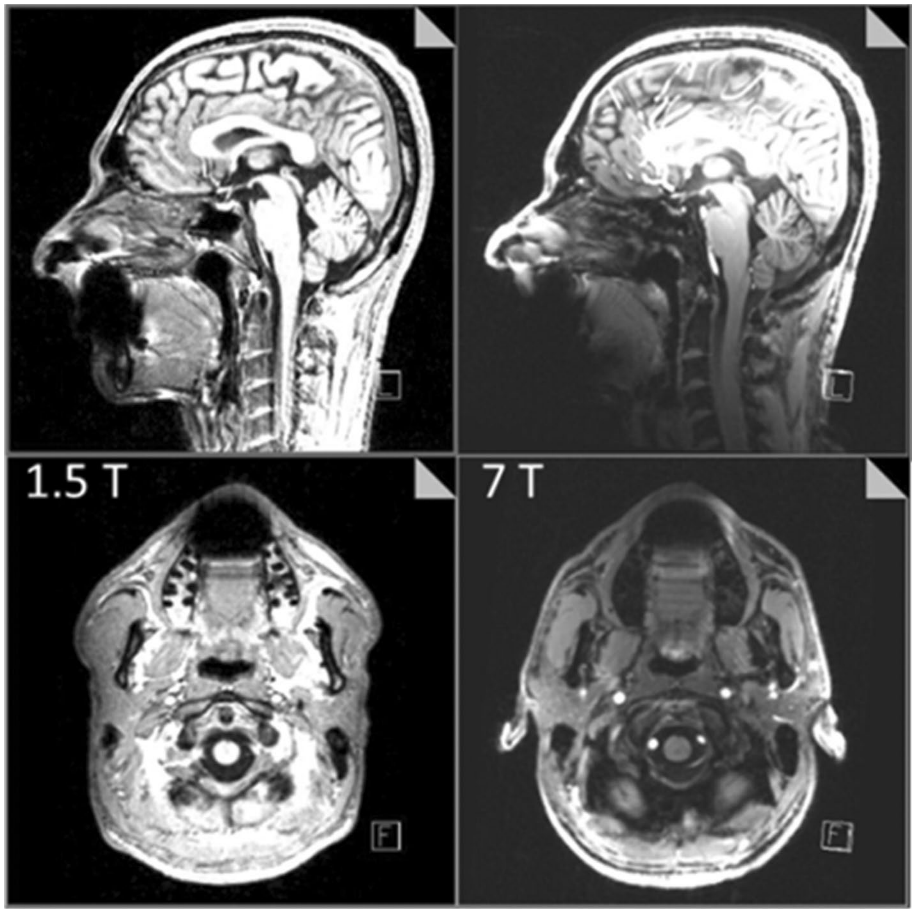


**Fig. 7** Comparison of MPRAGE images obtained at 1.5 and 7 T in a healthy volunteer (m, 38y) with a retainer wire behind the teeth. Both sequences were measured with 1-mm isotropic resolution and similar parameters (1.5 T: echo time (TE) 3.6 ms, bandwidth (BW) 360 Hz/pixel; 7 T: 2.0 ms, BW 210 Hz/pixel). Signal loss and incomplete inversion are visible. Subsequent SWI and EPI scans with focus on the cerebellum remained unaffected by the wire. At 7 T, the 32-ch coil (Nova Medical) was used. *Note* Window-leveling was adjusted to better demonstrate artifacts from the retainer wire

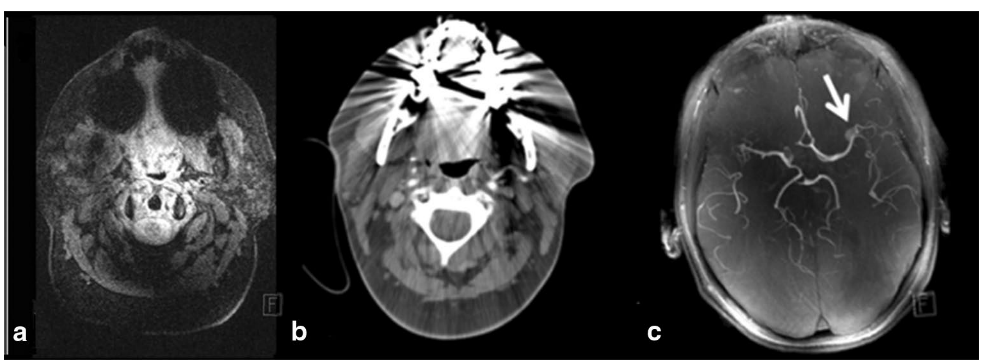


**Fig. 8** Images of a volunteer (f, 53y) with dental implants on the right and left side of her jaw. Strong signal loss around the implants is visible in the 7 T 3D-FLASH image (**a**), correlating well with a CT image of the patient (**b**). In **c**, the 7 T TOF angiography of the subject's aneurysm (*arrow*) remained artifact-free. The 7 T images were obtained with an 8-ch head coil (Rapid Biomed)

general, few implants have already been labeled "MR Conditional" at 7 T by utilizing ASTM standards [55]. Furthermore, as in all MR examinations, communication with the subjects should be maintained to enable them to indicate any trouble or discomfort during the scan. Also, an intensive interview with the subjects prior to the scans is highly recommended to identify all implants and their type. All implants scanned at our institution were either made of non-ferromagnetic material, mostly titanium, or made of non-metallic and non-conductive material, such as biopolymer screws. Titanium is a biocompatible material and has a low magnetic susceptibility ($\chi \approx 182 \times 10^{-6}$) [56] and is, therefore, an advantageous material for MRI. Forces and torques on implants as a consequence of the strong static magnetic field are significantly reduced with low magnetic susceptibility (diamagnetic and paramagnetic

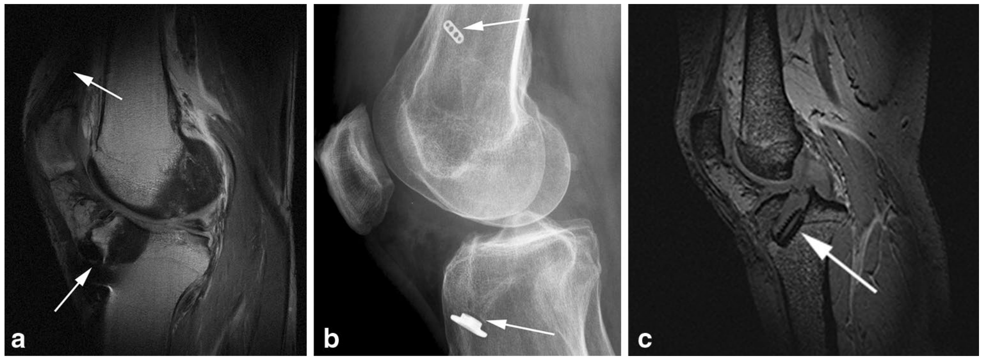


**Fig. 9** **a**, **b** Images obtained in a subject (m, 36 years) with two titanium endobuttons for the reconstruction of the ACL. Signal loss is clearly visible in the 7 T proton density (PD)-weighted turbo spin echo sequence (**a**, *arrow*). A corresponding CT image is given in (**b**). Endobuttons are clearly visible (*arrows*). **c** 3D-FLASH image obtained at 7 T in a patient (f, 25y) with a bioabsorbable polymer screw. The gradient echo sequence was measured with 1-mm isotropic resolution, TE 3.1 ms, and BW 200 Hz/pixel. The screw is clearly visible (*arrow*)

materials). A total-knee prosthesis was made of zirconium (also a non-ferromagnetic material), and a total-hip prosthesis was made of a cobalt-chrome-molybdenum (CoCrMo) alloy already tested "MR Conditional" at 3 T. For this implant, restrictions of the "MR Conditional" labeling regarding RF exposure with a transmit body coil were not applicable for the 7 T scans, where a distance of more than 30 cm was retained between the implant and local transmit head coil. Similarly, copper (IUD) and nitinol (stents) were also permitted to be exposed to the static magnetic field but not to be within the direct exposure volume of the RF coil. During the screening interview and prior to the research scan at 7 T, women with IUD were advised to see a gynecologist to ensure sufficient contraceptive protection after the 7 T scan. However, force measurements performed by Rauschenberger et al. [57] showed no deflection and no torque at 3 or 7 T for copper IUD. For the 2 volunteers with stents who were imaged with head coils, 1 had his stent in the femoral artery and the other reported 2 stents, 1 Y stent for repair of the abdominal bifurcation (more than 30 cm from the exposure of the transmit coil) and 1 coronary stent located 15 cm from the exposure volume of the coil. The latter was cleared for 7 T based on a study of Santoro et al. [8] and after evaluation of detailed implant information and previously obtained CT images that showed the exact location and dimension of the stent, as well as that only a single and not multiple stents had been used. It should be mentioned that some stents may be made of stainless steel [58] and should, therefore, to be excluded from any scan at 7 T. Some dental implants, such as retainer wires, are also suspected to contain magnetic stainless steel and, hence, to produce measurable displacement forces in the testing, according to the ASTM [59]. However, general experience with dental implant scanning shows a safe history even if some dental implants are made of ferromagnetic materials. In the group of subjects presented here, retainer wires that form closed loops were excluded from imaging at 7 T, and only straight wires up to 47 mm length were cleared. Implants made of non-metallic materials such as the Mirena and Nuvaring IUD and Teflon needles (Mini-Med Paradigm Pumps, Model 512, Medtronic) were not expected to generate any force or torque. For the infusion pumps, particular vigilance was observed in determining the needle material, since some needle material may be metallic [60]. RF field interactions with potentially metallic compositions of tattoo ink were considered to be unlikely under the condition that the tattoos were located outside the exposure volume of the transmit coil. Image artifacts were clearly visible at 7 T, especially for dental implants. However, the artifacts remained localized to the vicinity of the implants and did not impair the quality in the imaging areas of interest (Figs. 7, 8).

## Conclusion

In conclusion, our initial experience at 7 T indicates that an overly conservative exclusion of all subjects with implants and/or tattoos from 7 T examinations is not warranted. Nevertheless, imaging should only be performed in carefully selected subjects after acquiring substantial information to enable a proper risk assessment.

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**Compliance with ethical standards**

**Conflict of interest** MR:comp GmbH provided support in the form of salaries for authors Yacine Noureddine and Gregor Schaefers.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required.

**Informed consent** Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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