Safety Measurements for Heating of Instruments for Cardiovascular Interventions in Magnetic Particle Imaging (MPI) – First Experiences

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ABSTRACT

Magnetic particle imaging (MPI) has emerged as a new imaging method with the potential of delivering images of high spatial and temporal resolutions and free of ionizing radiation. Recent studies demonstrated the feasibility of differentiation between signal-generating and non-signal-generating devices in Magnetic Particle Spectroscopy (MPS) and visualization of commercially available catheters and guide-wires in MPI itself. Thus, MPI seems to be a promising imaging tool for cardiovascular interventions. Several commercially available catheters and guide-wires were tested in this study regarding heating. Heating behavior was correlated to the spectra generated by the devices and measured by the MPI. The results indicate that each instrument should be tested separately due to the wide spectrum of measured temperature changes of signal-generating instruments, which is up to 85°C in contrast to non-signal-generating devices. Development of higher temperatures seems to be a limitation for the use of these devices in cardiovascular interventions.

Keywords: magnetic particle imaging (mpi), cardiovascular intervention, safety aspects and heating, interventional devices, magnetic field

1. INTRODUCTION

Cardiovascular interventions have emerged as the minimally invasive therapy of choice for many diseases in clinical routine, e.g., coronary artery disease and myocardial infarction [1]. Today, X-ray fluoroscopy and X-ray-based digital subtraction angiography are predominately used for imaging in cardiovascular interventions. Due to increased indications, the number of such interventions

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performed has been increasing constantly. This fact and the need for repeated cardiovascular interventions in patients, e.g., those with chronic coronary artery disease, lead to an increased exposure to ionizing radiation of patients as well as physicians. Furthermore, X-ray fluoroscopy relies on iodine-based contrast agents and holds the potential risk of complications such as allergic reaction or acute renal failure. Despite these drawbacks, X-ray-fluoroscopy is the gold-standard imaging technique for cardiovascular interventions although other imaging modalities have been evaluated as alternatives.

Cone beam computed tomography (CT) allows three-dimensional imaging [2], but the need for iodized contrast media remains, and the radiation of cone beam CT is higher and its temporal resolution is lower compared to X-ray fluoroscopy. To achieve three-dimensional imaging without exposing patients to ionizing radiation, MRI-guided intravascular interventions could be an alternative to those imaging techniques [3]. However, MRI is not used for intravascular interventions in clinical routine yet, although it seems to be promising [4]. Artifacts of metalliferous clinical instruments are one of the main limitations for using MRI in cardiovascular interventions. Other limitations include the risks of radiofrequency [5–8] and gradient-induced heating [9]. A number of studies showed heating behavior of different commercially available interventional instruments in MRI guided interventions [5, 10–13]. These studies indicated the necessity of safety measurements for guide-wires and catheters to predict possible complications for instruments in intravascular interventions involving electromagnetic-field-based imaging methods.

Magnetic particle imaging (MPI) is a new 3D imaging method, introduced by Gleich and Weizenecker in 2005 [14]. MPI distinguishes itself by being completely free of ionizing radiation in contrast to X-ray fluoroscopy, digital subtraction angiography and CT. The principle is based on the nonlinear magnetic response of superparamagnetic iron oxide nanoparticles (SPIOs) in a sinusoidal oscillating magnetic excitation field. The modality is able to provide high temporal and good spatial resolutions and to directly quantify the spatial distribution of SPIOs [14–18]. This makes MPI a promising alternative to CT-fluoroscopy for cardiovascular interventions [19–21]. One precondition for cardiovascular imaging is *in vivo* real time imaging [17], i.e., visualization of vasculature and instruments with high temporal and spatial resolutions. Recent studies showed that visualization of devices in MPI is possible by an extinction of signal caused by interventional device itself, or alternatively, by labeling devices with SPIOs for MPI [22, 23]. Besides being able to visualize the instruments in real-time and with high spatial resolution, knowledge about the characteristics of the instruments with respect to safety in MPI is necessary. The aim of this work is to study the heating behavior of commercially available interventional instruments in MPI.

2. MATERIALS AND METHODS
2.1. MPI Scanner
MPI is based on the detection of the nonlinear response of iron oxide nanoparticles in an oscillating magnetic excitation field [14]. Using two rings of permanent magnets in a mirror-symmetric set-up (Figure 1b), a static magnetic gradient field,

the so-called selection field (dB$_z$/dz = 2.5 T/m and dB$_x$/dx = dB$_y$/dy = 1.25 T/m), is generated. The selection field exhibits a symmetric point with a zero magnetic field, named the *field free point* (FFP). At the FFP, the particles' magnetization is free to follow an excitation field. Outside the FFP, however, the particles are saturated and thus unable to follow the excitation field. As a consequence, they do not produce any MPI signal.

To determine the spatial distribution of the magnetic tracer material, MPI measures the magnetization change in the tracer material in a time-varying external magnetic field, the so-called drive field. The drive field itself has a defined amplitude and frequency (ω_0) and causes a changing magnetization M(t) of SPIOs which can be measured as an induced signal s(t) in receiving coils.

The relation between the external magnetic field and the magnetization is non-linear. The induced signal, therefore, includes the excitation frequency (ω_0) and also harmonics ($n\omega_0$). The presence of these harmonics indicates the presence of magnetic material and also carries the information about the spatial distribution and the quantity of the magnetic material. Furthermore, for reasonable concentrations, the measured signal is proportional to the SPIO-concentration. To acquire complete volumes, it is necessary to move the FFP through the volume and measure and analyze the harmonics.
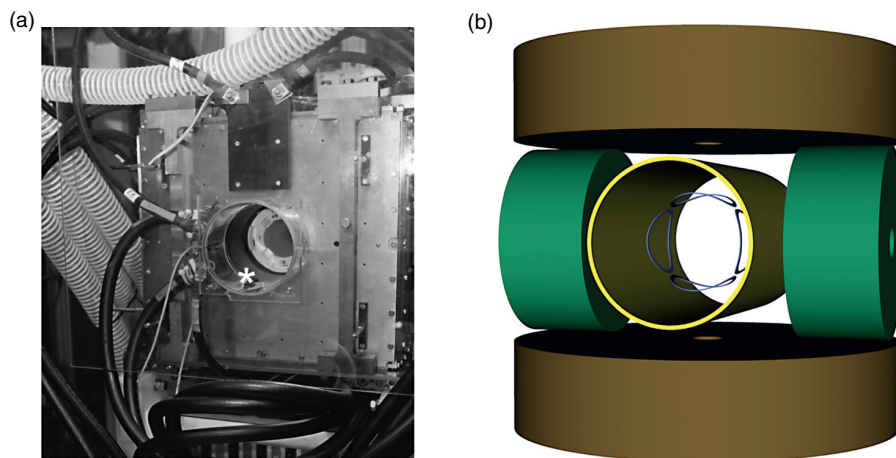

Figure 1.   (a) A view of the bore (indicated by *) of the experimental preclinical Magnetic Particle Imaging (MPI) demonstrator at Philips Research Laboratories, Hamburg, Germany. (b) An MPI scanner. The field of view is in the middle of a cylindrical bore (yellow). The brown coils (at the top and bottom) build a selection field and a drive field in vertical direction. Second drive field is generated by the green coils (left and right) in horizontal direction. Third pair of coils which generate a drive field along the bore in the horizontal direction is not shown. Two pairs of receiving coils (purple) are shown inside the bore.

This movement of the FFP is realized by drive fields. For this study, three drive field coils are placed in x, y, and z directions, respectively, generating oscillating, sinusoidal fields with peak amplitudes $B_{Dx} = B_{Dy} = B_{Dz} = 11$ mT at frequencies of 25.3, 26.0 and 24.5 kHz for the x, y and z channels, respectively. By moving the FFP through the complete field of view in three dimensions, it would be also possible to acquire three-dimensional images.

A more detailed description into MPI is given by Gleich and Weizenecker [14–17]. The setup used for this study, a preclinical MPI demonstrator, is presented in more details in Figure 1 and [24].

2.2. Interventional Devices

Based on studies of Haegele et al. [22, 23], eight commercially available interventional instruments were selected: 5 guide-wires and 3 catheters. Three of the 5 guide-wires were made of stainless steel (Amplatz Super Stiff 0.035", Cook Tapered Tefcor 0.035" and Boston Scientific, Platinum Plus, 0.018"), and the other two were made of Nitinol (Terumo Radifocus 0.035" and Terumo Progreat 0.021"). Two of the three catheters had a non-braided Tungsten-tip but a braided shaft, which was made of stainless steel (Boston Imager II 5F and Cordis Tempo Aqua 4F). The third catheter, Terumo Radifocus Glidecath 5F (Simmons/Sidewinder), was composed of double–braided stainless steel with hydrophilic coating. Interventional devices differed in composed materials, radiopaque markers and signal response in Magnetic Particle Spectroscopy (MPS), as shown previously [22]. A more detailed description of used interventional devices and their characteristics in MPI is listed in Table 1.

2.3. Positioning of the Instruments and Temperature Monitoring

A phantom of 30-cm length, made of acrylic glass and shaped to precisely fit into the bore of the MPI demonstrator, was used to ensure reproducible positioning of the devices in the bore of the setup. The phantom did not show any paramagnetic characteristics and thus did not contribute to the MPI signal. All instruments were inserted into the phantom through individual rubber-made introducers at the top of the phantom and each was positioned at the desired location by a custom-made positioning system (Figure 2). The catheters and guide-wires were inserted and positioned at the center of the phantom, while the temperature sensors were inserted peripherally and placed alongside the instrument at the desired points of temperature measurement. Three temperature sensors were placed at the tip of the interventional devices and at 5 and 10 cm distance from the tip. The fourth temperature sensor was placed inside the phantom without any contact to other sensors or interventional devices, to serve as a reference (Figure 2) for the temperature in the bore of the MPI demonstrator. The phantom was placed in the middle of the bore. Interventional devices were aligned in the longitudinal direction of the bore. Sinusoidal oscillating magnetic field was switched on continuously during placement of phantom and subsequent measurements.

Table 1. Different interventional devices in MPI, their radiopaque marker and material, and their potential to generate spectra in MPI in contrast to their heating behavior

Name	Device/Size	Radiopaque marker/ Material	Signal response in MPI	T_{max} in MPI
Guide-Wires				
Boston Scientific, Amplatz Super Stiff ™	Guide-Wire 0.035"	Stainless steel, PTFE coating	Yes	84.2°C
Boston Scientific, Platinum Plus ™	Guide-Wire 0.018"	Stainless steel	Yes	22.0°C
Cook Medical Tapered Tefcor	Guide-Wire 0.035"	TFE coated stainless steel	Yes	53.1°C
Terumo Radifocus® M Standard Type	Guide-Wire 0.035"	Nitinol, polyurethane, Tungsten	None	22.0°C
Terumo Progreat®	Guide-Wire 0.021"	Nitinol, gold coil	None	22.0°C
Catheters				
Boston Imager™ II	Catheter 5F (Vertebralis)	Tip: non-braided; Shaft: stainless steel Radiopaque marker: Tungsten	Yes	22.0°C
Cordis TEMPO® AQUA®	Catheter 5F (Pigtail)	Tip: non-braided; Shaft: stainless steel Radiopaque marker: Tungsten	Yes	34.2°C
Terumo Radifocus® Glidecath®	Catheter 5F (Simmons)	Polyurethane Double braided stainless steel	None	22.0°C

Temperature monitoring was performed continuously using a four-channel Gallium-Arsenide (GaAs)-based fiber optic temperature measuring system (FOTEMP4, Optocon AG, Dresden, Germany). Temperatures were shown on an LCD display and transmitted via RS-232 communication port for real-time data acquisition
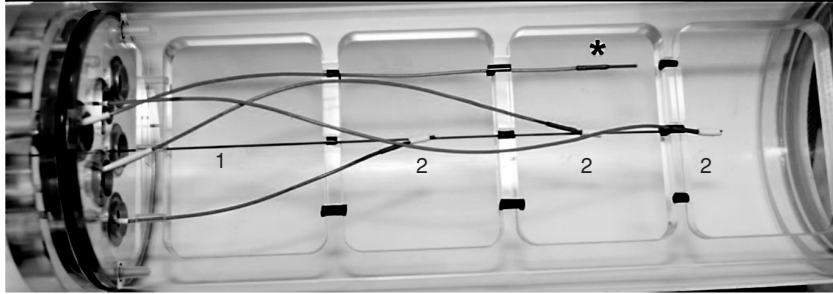
Figure 2.   Phantom made of acrylic glass with denoted positions of fiber-optic temperature sensors (2) along the guide-wire (1) at the center of the phantom. The (*) denotes an additional sensor used as a reference without any contact to other sensors or guide-wires.

using FOTEMP-Assistant software for the Win7 operating system of a laptop PC. During excitation, temperature was monitored and recorded every 0.5 seconds for every position for each tested device. Data acquisition was performed until the temperatures reached steady state for more than 2 minutes. Additionally, thermography monitoring was performed by using a thermographic camera (testo 875-2i set, Testo AG, Lenzkirch, Germany).

3. RESULTS

Outside the scanner, the room temperature was at 26°C. The temperature inside the MPI demonstrator was measured at a constant 22°C, maintained by an integrated cooling system. Consequently, the reference sensor was also cooled down to 22°C in all cases, starting from the moment when the phantom was placed inside the scanner. Only one of the three other sensors attached to the investigated device along the longitudinal axis of the bore was at the field free point (FFP) at one time. The other two sensors, which were 5 and 10 cm distant from the area of the FFP, cooled down to 22°C in all cases, comparable to the reference sensor. Temperature measurements at the sensors attached to the part of the instrument, which was placed at the FFP, showed significantly different, device-specific behavior than the sensors away from the FFP.

3.1. Non-signal-generating devices

All non-signal-generating devices showed similar heating characteristics during MPI operation. Both Terumo Guide-wires and Terumo Radifocus Glidecath catheter did not show any temperature increase. Each of the three attached sensors cooled down to 22°C, compared to the measured 26°C room temperature outside the scanner (Figure 3a). No increase of temperature was observed, particularly not at the FFP for any device during the entire measurement. The duration of the cooling process was less than 4 minutes for all three devices. It was not possible to detect any hot spot along the guide-wires and
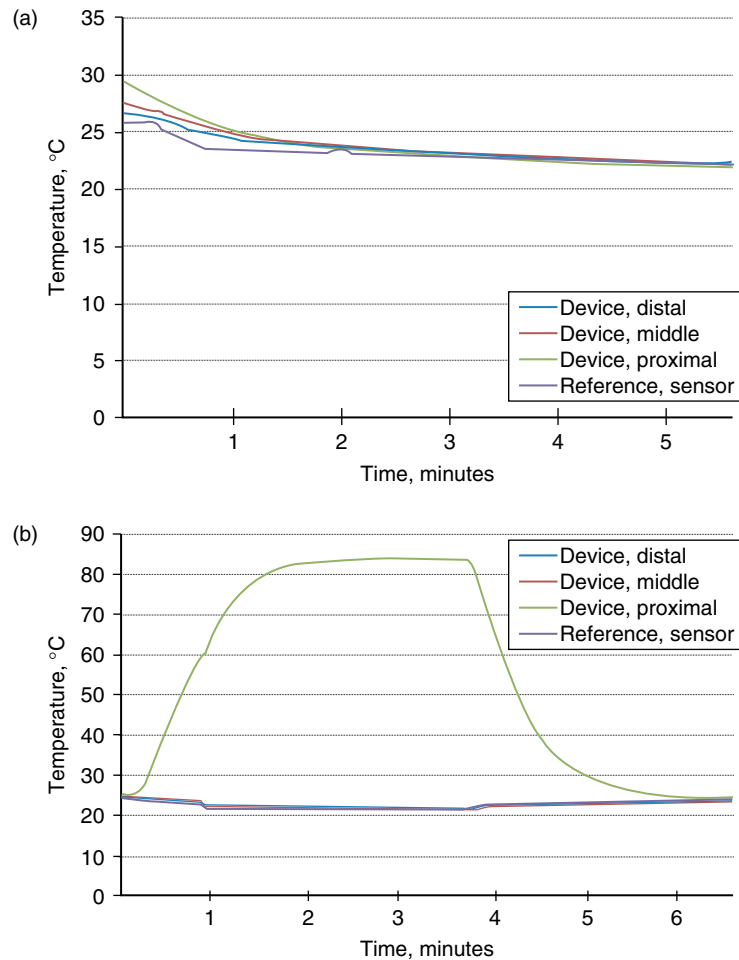
Figure 3.   (a) Temperature change of a non-signal-generating device. The observed cooling is due to the low temperature inside the imaging setup, generated by a dedicated cooling system. (b) Temperature change of a signal-generating device with a peak of 85°C reached within 2 minutes.

catheters using the thermographic camera (Figure 4). Simultaneously measured MPI signals were similar to the reference MPI signal of the empty setup (Figure 5 a, b), again confirming the non-signal-generating characteristics of the tested devices [22].

3.2. Signal-generating devices
Although, generally, signal generating devices showed a detectable MPI signal (Figure 5c), different heating patterns were recorded. Differences were observed in the magnitude of peak temperatures and peak times.
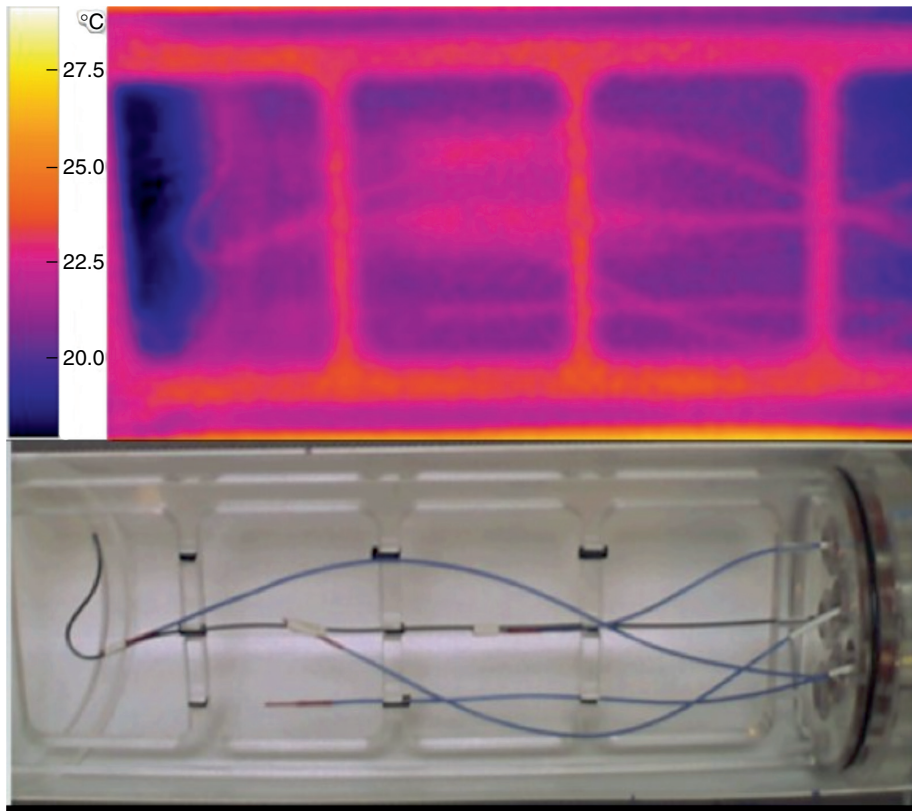
Figure 4.   Thermograph of a non-signal-generating device (above, right) with temperatures of approximately 22°C (above, left). The position of the fiber-optic sensor corresponds to the field free point (FFP) inside the scanner. No hot spot or heating can be observed.

For all devices showing heating inside the demonstrator, heating at the FFP started at the moment the device was placed in the bore of the scanner. The highest temperature was observed for the Amplatz Super Stiff Guide-Wire, which reached 85°C within 2 minutes at the FFP (Figure 3b). The cool-down time for the guide-wire when it was removed from sinusoidal oscillating magnetic field was nearly as short as the time that was needed to heat up. Fifty-five seconds after removing the Amplatz Superstiff from the FFP, the temperature was lowered to 37°C. One minute later, the sensor detected 26°C at the former hot spot. The longest time to peak was observed for the shaft of Boston Imager II Pigtail catheter (3 min). The maximum temperature was 34.2°C. The tip did not show any heating at all when it was placed at the FFP. Cook Tapered Tefcor guide-wire 0.035" achieved a maximum temperature of 52.3°C. The data from the thermographic camera proved that all
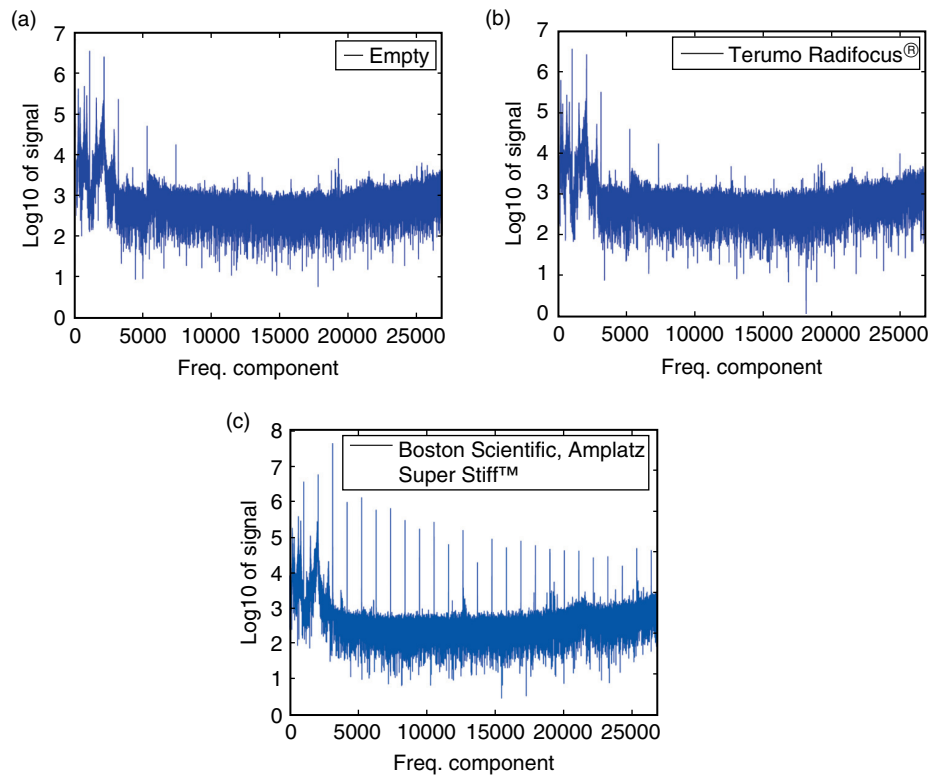
Figure 5.   (a) Measured signal with no material inside the bore of the imaging setup, used as a reference background for the assessment of signal-generating and non-signal generating devices. (b) Measured signal of Terumo Radifocus® M Standard Type, a non-signal-generating device, similar to the reference without peaks. (c) Measured signal of Boston Scientific Amplatz Super Stiff ™, a signal-generating device, showing amplitude peaks.

devices featured punctiform hot spots exclusively at the FFP and no heating at all away from the FFP (Figure 6). When the temperature sensors were removed from the FFP, temperatures decreased to 22°C, the ambient temperature inside the MPI demonstrator.

Two of the tested signal-generating devices, the Boston Scientific Platinum PLUS guide-wire and the Boston Imager™ II catheter, showed no increase in temperature, neither at the FFP nor in its vicinity, although they showed a detectable MPI signal. Thus, the thermal behavior of these two instruments did not correlate with the former categorization of signal-generating and non-signal-generating instruments [22].
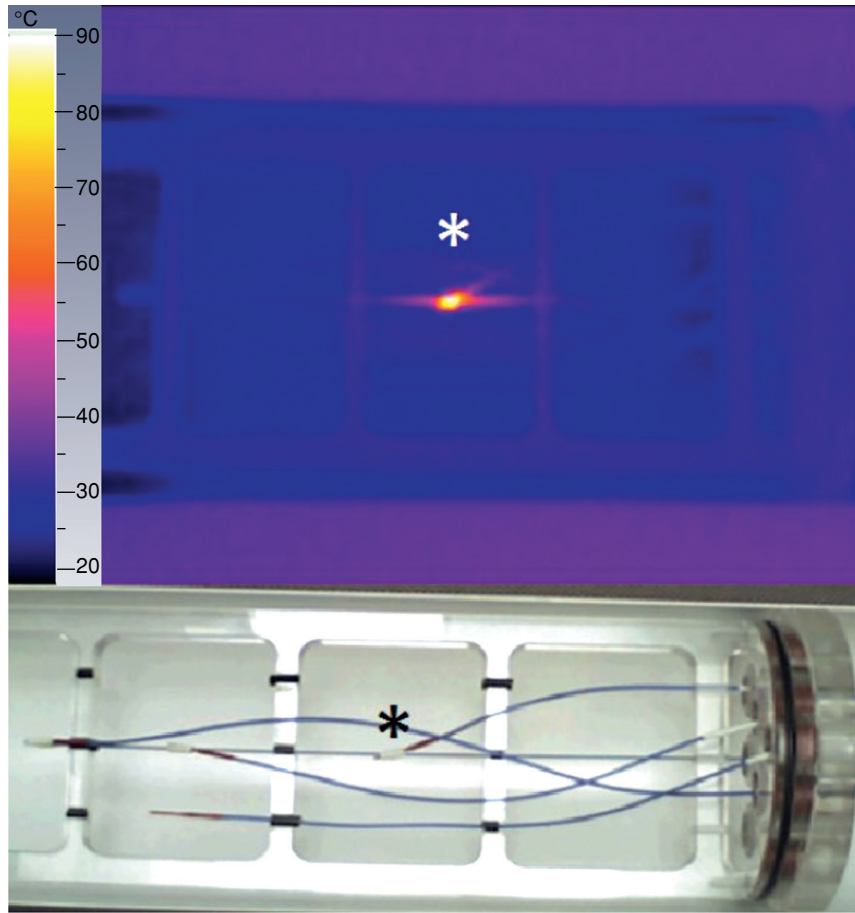
Figure 6.   Thermograph of a signal-generating device (above). The fiber-optic temperature sensor is located at the hot spot (*), which is at the field free point (FFP) inside the setup. Other sensors did not measure any heating and no other hot spots were detected along the guide-wire.

4. DISCUSSION

This study provides, to the best of our knowledge, the first security measurement regarding heating of interventional instruments in MPI. The selection of evaluated instruments was based on the most utilized instruments in our institution as well as on results from prior studies of Haegele et al. in 2012 [22]. Haegele was able to distinguish between "signal-generating" and "non-signal-generating" devices. Non-signal-generating instruments did not show any temperature increase at all, either at the FFP or in its vicinity. Terumo guide-wire ("M standard type") does not contain any distal radiopaque tip marker and its core material is Nitinol. Different from the guide-wire "M

standard type," the Terumo "Progreat" has a 3-cm gold coil as a distal radiopaque marker while its core material is Nitinol as well. Based on the utilized material, neither MPI signal nor an increase of temperature was expected.

Terumo Radifocus "Glidecath" catheter contains a double-braided stainless steel core with a polyurethane jacket. Although the device contains stainless steel, no remarkable signal was generated, as Haegele et al. has already shown. However, there was no temperature rise either. As described previously, it is assumed that the composition of metals is responsible for the signal properties and the non-ferromagnetic characteristics of these devices, which may explain no heating. Furthermore, prior to the use of these catheters in an interventional MPI setting, they must be made visible and clearly distinguishable from background noise and from intravascular tracers, which in turn could possibly create new problems.

Several methods of labeling non-signal-generating devices with SPIOs have been described previously and have shown promising results [22, 23]. In general, active and passive visualization approaches can be distinguished. The latter seems to be more easily accessible and can be achieved by oppositional passive opacification of the vessel lumen using intravascular iron-oxide contrast agent [22, 23]. Their contrast mechanism relies on the cancellation of signals by the interventional instruments themselves.

In contrast, the active visualization of non-signal-generating instruments is also a promising approach. One possibility to actively generate a signal is filling of existing voids, i.e., balloons, within the catheter with SPIOs solutions. Labeling of devices with an SPIO-based enamel is also feasible and has been described in a previous study [22]. However, heating behavior of those SPIO coated devices is not yet known. Indeed, an AC magnetic field holds the risk of inducing current, e.g., for conductive devices which have ferromagnetic characteristics. However, the development of hazardously high temperatures caused by SPIO labeled devices seems improbable as the needed concentrations of SPIOs will most likely not be high enough.

Regarding the results of the signal-generating instruments, it seems to be plausible to categorize these instruments into two sub-groups. One sub-group includes those devices which show the expected heating due to integrated ferromagnetic material and those which do not show any heating at all, although they generate a signal in MPI. However, the majority of catheters showed a temperature rise. One catheter showed an increase up to 85°C and therefore seems not suitable for cardiovascular interventions due to safety concerns, i.e., intravascular protein denaturation, which can result in thrombogenic events or damage of the vascular wall. Intravascular cooling might mitigate the heating effects of these interventional devices *in vivo*, but has not been tested so far. Overall, it seems to be necessary to discriminate non-signal-generating instruments and signal-generating instruments without heating from those signal-generating instruments causing heating.

Ferromagnetic characteristics might seem to be the main reason for generation of an MPI signal in the devices listed above. These characteristics lead to hysteresis losses while changing magnetization in sinusoidal magnetic fields. Most likely, the broad range of heating may result from different hysteresis losses due to different ferromagnetic behavior of compositions of metal used as radiopaque markers, and those

different compositions may result in different ferromagnetic characteristics. The fact that some catheters which generate signal in MPI do not show any heating remains unclear. A possible explanation is the presence of eddy currents, which are well known from MRI. Eddy currents are generated in magnetic fields in metalliferous implants. It may be possible that these currents are the reason for the MPI-signal detected in some devices (e.g., Boston Scientific Platinum PLUS guide-wire and Cordis Tempo Aqua Vertebralis catheters) without inducing any heating at all in opposition to the devices with ferromagnetic characteristics which show both MPI signal and heating. Eddy currents can cause detectable MPI-signals without heating. In contrast, eddy currents result in heating if current flow is influenced by high resistance, e.g., in contact points of different materials in devices. Furthermore, it seems possible that the induction of eddy currents could influence heating behavior of metalliferous devices even more for other frequencies than 25 kHz, as they were used in this study. For instruments which do not show any MPI signal, the situation still seems to be unclear. Heating of instruments without any observed signal in MPI does not seem to be plausible at first, yet it is not impossible. In theory, heating caused by eddy currents is also possible in non-signal-generating devices, especially when complex devices (e.g., metalliferous stents) are used. In those cases, linear eddy currents could be induced and a measurable MPI signal could be missed. Taking heating due to eddy currents into account, heating of non-signal-generating devices seem to be possible. This suggests the necessity of further studies for non-signal-generating devices at different frequencies.

Recent studies indicate the risk of peripheral nerve stimulation using MPI at frequencies of 25 kHz [25] while a secure threshold seems to be achievable at frequencies above 100 kHz [26]. Due to limitations related to peripheral nerve stimulation thresholds and tissue heating, future MPI scanners may operate at frequencies different from 25 kHz. Thus, instruments should be tested for all relevant excitation frequencies, which may range from 5 to 500 kHz.

In fact, heating behavior in MPI is a complex phenomenon which is not fully understood to date. The behavior of devices in MPI seems to be dependent on both ferromagnetic characteristics and composition of devices; thus, it is not possible to reliably predict whether an instrument that contains ferromagnetic material will show a rise in temperature in MPI or not.

Concerning safety aspects, several studies showed different behavior of different interventional instruments in MRI and declared the necessity of safety/heating measurements for each available device [5, 10–13]. The results of this study suggest further studies to predict the risk of interventional instruments for cardiovascular applications in MPI. Furthermore, each device should be tested individually before being used in interventional applications in MPI, as this study clearly shows that inconclusive and unpredictable heating characteristics for signal-generating instruments exist.

5. CONCLUSIONS

Cardiovascular interventions seem to be a promising application for MPI, providing good spatial and high temporal resolutions without exposure to ionizing radiation. Besides visualization of interventional instruments, safety aspects are one of the preconditions and a topic of ongoing research. Utilization of instruments containing metal, such as catheters, guide-wires or stents seems to be a limitation for some of the

signal-generating devices due to their heating behavior in MPI. Cardiovascular interventions seem to be safe and very promising by using non-signal-generating catheters coated or loaded with SPIOS, or those signal-generating devices which do not show any heating behavior in MPI. However, it remains unclear to what extent eddy currents will cause rise in temperature. Consequently, additional experiments must be performed to further study safety aspects for MPI guided cardiovascular interventions.

ACKNOWLEDGEMENTS

CONFLICT OF INTEREST
The authors indicated no potential conflicts of interest.

NOMENCLATURE
B magnetic (induction) field, T
B_{Dx} amplitude of magnetic drive field in x-direction, T
B_{Dy} amplitude of magnetic drive field in y-direction, T
B_{Dz} amplitude of magnetic drive field in z-direction, T
FFP Field Free Point
$M(t)$ magnetization (as a function of t)
$s(t)$ induced signal (as a function of t)
t time

Greek
$n\omega_0$ frequencies of the harmonics of the excitation frequency
ω_0 excitation frequency

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