# Guideline
# Use of MRI in patients with implants

This is the English translation of the Dutch guideline
'richtlijn Gebruik MRI bij patienten met implantaten'.
The Dutch version is officially approved by the Dutch Association of Medical Specialists (FMS)

**INITIATIVE OF**
Society for Medical Physics of the Netherlands (NVKF)

**IN COLLABORATION WITH**
Dutch Society for Medical Imaging and Radiotherapy(NVMBR)
Netherlands Society of Cardiology(NVvC)
Netherlands Society for Neurosurgery(NVvN)
Radiological Society of the Netherlands(NVvR)

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**Colophon**

GUIDELINE USE OF MRI IN PATIENTS WITH IMPLANTS


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## Contents

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# General introduction

**Motivation for the guideline development**

Every year more than 750,000 implants are placed in the Netherlands (van der Graaf, 2016). This number increases over time and more and more different types of implants are employed in an increasing number of pathologies. Many patients with implants will later on in life be referred for a diagnostic MRI examination, a technique that is increasingly used in clinical routine (RIVM, 2015). Based on current information on MRI contraindications of implants, an implant is either classified as 'MR safe' (MRI can be applied without risk) or 'MR conditional' (where MRI can take place safely under specific conditions), or into the category 'MR unsafe'. The additional risk of complications due to the presence of the implant is negligible for the categories 'MR safe' and 'MR conditional'. However, the classification of implants is performed by the implant manufacturer, who sometimes tests the implant in a limited setting and tends to define conservative conditions. In addition, the above classification assumes that one always knows all details of the implant, which is not always the case in clinical practice.

There is a lack of sufficient information in the clinic to properly determine whether the importance of an MRI examination for the patient with an implant that is not guaranteed to be MR safe or conditional outweighs the risk for that patient with respect to the loss of diagnostic information resulting from denying the MRI examination. This guideline provides an advice on how to deal with this trade-off for specific types of implants and, in some cases, to deviate from the conditions set for MRI by implant manufacturers.

**Purpose of the guideline**

The aim is to improve and guarantee the quality of the MR safety expert's advice to the medical proffesional, thus ensuring safety and access to MRI examinations for patients with implants. This guideline focuses on implants for which it is not entirely clear whether or not an MRI exam is safe, with the aim of making a risk assessment. In addition, the guideline aims to save time in practice as modules for certain implants provide recommendations for generic policies, eliminating the need to obtain further information about the specific implant model for each individual case.

With this guideline, therefore, a better estimation of the health risk of an MRI examination in a patient with an implant can be made and compared to the potential health benefit of the MRI exam for that patient.Currently different hospitals have varying policies in case of implant information lacking with respect to whether the patient can be scanned, and if this is the case, with respect to which (conservative) scan conditions should be applied. This guideline can therefore result in improved availability of MRI for certain patients and in certain hospitals, and in other cases or hospitals it could result in a better substantiated advice of possible limitations for the MRI exam.

**Demarcation of the guideline**

This guideline assumes that the hospital in which it is applied has a well-functioning MRI safety policy in place, based on good practices adopted worldwide to create a safe environment around MRI systems (Kanal, 2013; Cross, 2018; Sammet, 2016). Within the framework of such a policy, for example, each patient is screened for possible contraindications for undergoing the MRI scan prior to that examination.

This guideline is intended to be used when patients are referred for an examination on a whole body MRI scanner with horizontal closed bore superconducting magnet with a field

strength of 1.5 or 3 Tesla (T) and have an implant, according to the individual screening of the patient prior to the MRI examination. The systems chosen cover more than 95% of all diagnostic MRI systems in the Netherlands. Other types of MRI systems are not considered.

The first version of this guidelineline contains two modules:
*Module "MRI in patients with a cerebral aneurysm clip"*

- Some old types of cerebral aneurysm clips are an absolute contraindication for MRI, and can be fatal to the patient. Importantly, it is not always possible to determine exactly what type of clip was implanted in a patient, and therefore whether there is a risk. This module focuses specifically on the question of how to properly assess this risk in that case. Tthe module describes the MRI safety policy for patients with a cerebral aneurysm clip.

*Module "MRI in patients with a prosthetic heart valve, annuloplasty ring or mitra clip"*

- Many different types of prosthetic heart valves and annuloplasty rings exist, with a large number of those implants being 'MR conditional' with different conditions per type. The manufacturer of the implant has the freedom to specify the conditions, resulting in a wide variety of conditions. In addition, these conditions are often quite conservative, as a result of which some risks are overestimated. There are obvious differences in policy on how to scan patients with prosthetic valves between hospitals in the Netherlands. The aim of this guideline is to define a clear and unambigious guideline for MRI scans of patients with a prosthetic heart valve, annuloplasty ring or mitraclip.

**Intended users of the guideline**
The guideline is written for use by MR safety experts such as medical physics experts. In addition, the guideline may be informative to all professionals involved in planning MRI in patients with implants, i.e., radiologists, MR technologists and physicians referring for MRI.

**Structure of the considerations in the modules**
In addition to scientific literature, the information provided by manufacturers on the MR safety of their implants is of importance. This information is described in the MR safety databases of implants: partly in the freely accessible database of Prof. Frank Shellock www.MRIsafety.com, and partly in the commercial database of MagResource (MR:comp GmbH, Gelsenkirchen, Germany). A relevant summary for each module is included at the beginning of the considerations.

In addition, information from databases containing incident reports is important for this guideline. For each module relevant databases have been searched.

Finally, the considerations of each module have a fixed structure because the risks, when scanning patients with implants in the MRI scanner, can in general be classified as follows:

1. Risk of displacement and rotation of the implant due to the presence of the static magnetic field and the spatial gradient of this field.
2. Risk of implant heating due to interaction with the applied radio frequency (RF) field.
3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal.
4. Artifact in the MRI image.
5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner.
6. Risk of interference with implant function.

**Definitions and terms**

For implants the general international terminology of (ASTM, 2013) is followed:

- MR safe: an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
- MR conditional: an item with proven safety in the MR environment within defined conditions. At a minimum, the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields should be addressed. Additional conditions, including specific configurations of the item, may be required.
- MR unsafe: an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

However, not all implants can be classified into these categories. For example, an implant that does contain metal and has not been proven to be safe, but that is known not to pose any unacceptable risk to the patient.

The 2013 ASTM definition was used while drafting this guideline. Notably older literature is based on an older definition for which reason one can encounter devices being declared 'MR safe' in that literature whereas - according to the newer ASTM definitions - they are now labeled 'MR conditional' (e.g. limited to 1.5 T). In the literature summaries in this guideline the above mentioned 2013 ASTM definition is used and the text from older publications has therefore been rephrased whenever appropriate.

MR allowed for 1.5 and 3 T

This guideline uses the additional term 'MR allowed for 1.5 and 3 T'. This is a form of MR conditional where the use of MRI in patients with these implants is allowed when using a whole body MRI system with a horizontal closed bore superconducting magnet with a field strength of 1.5 T or 3 T without further conditions.

MR safety expert

The MR safety expert (MRSE) is specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice these are often medical physics experts with subspecialty Radiology and Nuclear Medicine and with sufficient knowledge of MRI, or physicists specialized in MRI.

MR safety officer

The MR safety officer (MRSO) as specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice, for human MRI systems this is often a specialized MR technologist.

Classification of risk estimation

The severity of a risk is typically quantified by the probability of its occurrence on the one hand and the severity of the harm on the other hand.

For the severity of the injury, the classification is based on NEN-EN-ISO 14971 (NEN, 2012). This standard describes risk management for medical devices. However, the classification has been simplified into 2 categories with the definition of calamity as given in the NEN 8009 standard on safety management systems for hospitals (NEN, 2018), see table 1.

**Table 1: qualitative description of severity of implant risk**

| Generic term | Description |
|---|---|
| Calamity | Fatal or permanent effects (other than scars) |
| Moderate | Restorable or minor injury or loss of function |

For the probability that a complication will occur in an individual MRI examination, the following classification from the NEN-EN-ISO 14971 standard (NEN, 2012) has been used, see table 2. This has been further specified with a quantitative translation into the probability of occurrence, because clinical risks when withholding an MRI examination are sometimes (only) known in qualitative measures. This makes it possible to make a better assessment by comparing both probabilities.

**Table 2: qualitative description and quantitative translation of probability**

| Qualitative description | Quantitative translation into chance |
|---|---|
| To be expected | 0.1 to 1 |
| Unusual | 0.01 to 0.1 |
| Rare | 0.001 to 0.01 |
| Unlikely | < 0.001 |

If multiple risks of complications are identified, it has added value to present the risks in a matrix, see table 3.

**Table 3: example of a risk matrix in which two risks are presented**

| | | **Severity** | |
|---|---|---|---|
| | | Moderate | Calamity |
| **Probability** | To be expected | *R1* | |
| | Unusual | | |
| | Rare | | *R2* |
| | Unlikely | | |

## References


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## Accountability

**Guide to the reader**
The text below will be included in the Guidelines database (www.richtlijnendatabase.nl) after completion of the comment and authorisation phase. References to "related products" can be found in the current version of the guideline text as separate chapters (see table of contents of the guideline).

Only the Dutch version of this Guideline was used for authorization. The guideline was subsequently translated into English in order for the international community to take note of the content of the Guideline.

**Methodology of the guideline development**
Validity and maintenance
While drafting the guideline, the working group made an estimate of the period after which reassessment should take place and defined points of attention for a future revision (update). The validity of the guideline module lapses earlier if new developments give rise to start a revision process.

| Module | Coordination[1] | Year of Authorization | Next assessment of validity module [2] | Frequency of review on validity[3] | Who supervises validity [4] | Relevant factors for changes in recommendation [5] |
|---|---|---|---|---|---|---|
| Prosthetic heart valve, annuloplasty ring or mitraclip | NVKF | 2019 | 2024 | Every five years | NVKF | New literature |
| Cerebral aneurysm clip | NVKF | 2019 | 2024 | Every five years | NVKF | New literature |

The other scientific associations participating in this module or users of the guideline share the responsibility and inform the association taking the primary responsibility for the module of relevant developments within their field of expertise that might impact the validity of the module

Authorization
The guideline module is authorized by the Dutch Association of Medical Specialists (FMS), and more specifically by the *Society for Medical Physics of the Netherlands (NVKF); Dutch Society for Medical Imaging and Radiotherapy (NVMBR); Netherlands Society of Cardiology (NVvC); Netherlands Society for Neurosurgery (NVvN); Radiological Society of the Netherlands (NVvR).*

General data
The guideline development was supported by the Knowledge Institute of the Federation Medical Specialists (www.kennisinstituut.nl) and was financed by the Foundation Quality

[1] Coordinator of the module (this can differ per module and can also be shared)
[2] Maximum after five years
[3] (Semi-)yearly, once in two years, once in five years
[4] Directing association, shared directing associations, or (multidisciplinary) working group that is maintained
[5] Ongoing research, changes in compensation/organization, availability of new resources

Funds for Medical Specialists (Stichting Kwaliteitsgelden Medisch Specialisten: SKMS). The funder had no influence whatsoever on the content of the guideline.

**Declarations of interest**

The Royal Dutch Medical Association-code to prevent conflicts of interest has been followed. All working group members have provided written statements whether they have had direct financial interests (relations with commercial companies, personal financial interests, research financing) or indirect interests (personal relationships, reputation management, and interests related to knowledge valorisation) in the past three years. An overview of the statements by working group members about any potential conflicts of interest and the opinion on how to deal with possible interests can be found in the table below. The signed declarations of interest can be requested from the secretariat of the Knowledge Institute of the Federation Medical Specialists.

| Working group member | Appointment | Additional appointments | Reported interests | Action taken |
|---|---|---|---|---|
| Götte | Cardiologist, Amsterdam UMC | Cardiologist, Cardiologie Centra Nederlands zero-hour appointment, paid | None | None |
| van der Graaf | Medical physics expert at RadboudUMC | None | None | None |
| Hofman | Medical physics expert, Amsterdam UMC | None | Involved in MRI research VUmc, basic reputation within the NVKF in the field of MRI | None |
| Kappert | System Specialist MRI, UMCG | Chairman Section MRI of NVMBR (unpaid)<br>Until autumn 2018 member of the NVMBR Board of Governors (unpaid)<br>Guest lecturer at Hanze University of Applied Sciences - MBRT (paid) | None | None |
| Kloeze | Medical physics expert Catharina Hospital | Member Mec-u (medical ethics committee) paid | None | None |
| Kuijer | Medical physics expert, Amsterdam UMC | None | Involved in scientific research projects using MRI. This does not concern research into the safety or function of implants. Reputation within the NVKF as medical physics expert with focus on MRI | None |
| Lavini | MRI physicist, Amsterdam UMC | None | None | None |
| Muller | Medical physics expert, Antoni van Leeuwenhoek Hospital | None | None | None |

| | | | | |
|---|---|---|---|---|
| Nierop | Medical physics expert, UMC Utrecht | None | None | None |
| van Pul | Medical physics expert, Maxima Medical Center | Part-time appointment at TU Eindhoven - technical physics. | Participation in NWO-TTP-sponsored research into alarm reduction in neonatal intensive care. TU Eindhoven and Philips Research-Patient Monitoring Group are involved in this project. This project has NO relation with this guideline. | None |
| Stam | Medical physics expert in training, Amsterdam UMC | Unpaid: visitator for the College of Testing of the Dutch Medical Physicist Training Foundation (OKF). | None | None |
| Teeuwisse | MRI physicist, C.J. Gorter Center for High Field MRI, LUMC, Safety Expert MRI | None | None | None |
| Vonken | Radiologist, UMC Utrecht | None | None | None |
| van der Zwan | Neurosurgeon, UMC Utrecht | None | None | None |

**Input patient's perspective**
No patient (representative) participated in the working group. The concept guideline has been submitted for feedback during the comment phase to the Patient Federation of the Netherlands.

**Implementation**
In the different stages of the development process, the implementation of the guideline and the practicability of the guideline were taken into account. The factors that could facilitate or hinder the introduction of the guideline in clinical practice have been explicitly considered. The implementation plan can be found with the Related Products.

**Working method**
AGREE
This guideline has been developed according to the requirements of the report Guidelines for Medical Specialists 2.0 by the advisory committee of the Quality Council. This report is based on the AGREE II instrument (Appraisal of Guidelines for Research & Evaluation II; Brouwers, 2010; www.agreetrust.org), a broadly accepted instrument in the international community, and on the national quality standards for guidelines: "Guideline for guidelines"(www.zorginstituutnederland.nl). For a step-by-step description of how an evidence-based module is created, we refer to the step-by-step plan Development of Medical Specialist Guidelines of the Knowledge Institute of the Federation Medical Specialists.

Identification of subject matter
Within the NVKF an analysis with a limited scope has led to the choice to develop these two modules.

Clinical questions and outcomes

The clinical questions were formulated by the chairman, working group members and the advisor. Subsequently, the working group inventoried which outcome measures are relevant for the patient, looking at both benificial and harmfull effects. The working group valued these outcomes according to their relative importance in the decision-making around recommendations, as critical (critical for decision-making), important (but not critical) and unimportant. The working group also defined, at least for the critical outcome measures, which differences they considered clinically relevant (to the patient).

Strategy for search and selection of literature

For the separate clinical questions, specific search criteria were formulated and published scientific articles were searched in (several) electronic databases. Furthermore, studies were scrutinized by cross-referencing for other included studies. The studies with potentially the highest quality of research were looked for first. The working group members selected literature in pairs (independently of each other) based on title and abstract. A second separation was performed based on full text. The databases, search terms and selection criteria are described in the modules containing the clinical questions. The search strategy can be retrieved from the Guidance database, see the tab 'Search accountability' for further details.

Quality assessment of individual studies

Individual studies were systematically assessed, based on methodological quality criteria that were determined prior to the search, so that risk of bias could be estimated. This is described in the "risk of bias" (RoB) tables. The RoB instruments used are validated instruments recommended by the Cochrane Collaboration:

- AMSTAR - for systematic reviews.
- Cochrane - for randomized controlled studies.

Summarizing of literature

The relevant research findings of all selected articles are shown in evidence tables. The most important findings from literature are described in summaries.

Grading quality of evidence and strength of recommendations

The strength of the conclusions of the scientific publications was determined using the GRADE-method: Grading Recommendations Assessment, Development and Evaluation (see http://www.gradeworkinggroup.org/ ) (Atkins, 2004).

GRADE defines four levels for the quality of scientific evidence: high, moderate, low or very low. These levels provide information about the certainty of the conclusions drawn in a study. (http://www.guidelinedevelopment.org/handbook/ ) (Schünemann, 2013).

| GRADE | Definition |
|---|---|
| High | • We are very confident that the true effect lies close to that of the estimate of the effect.<br>• It is highly unlikely that the conclusion changes when results of new large scale research is added to the literature analysis. |
| Moderate | • We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.<br>• It is possible that the conclusion changes when results of new large scale research is added to the literature analysis. |
| Low | • Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.<br>• There is a resonable chance that the conclusion changes when results of new large scale research is added to the literature analysis. |
| Very low | • We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.<br>• The literature conclusions are unsure. |

In the grading the quality of evidence of the scientific literature in the guideline according to the GRADE-method the borders of clinical desicions play an important role(Hultcrantz, 2017). Crossing these borders would lead to a change in the recommendations. To asses these borders of clinical descisons all relevant outcome measures and considerations should be taken into account. Therefore, these borders are not one to one comparable to the Minimal Clinically Important Difference (MCID). Especially, in situations in which an intervention has no important disadvantages and costs are relatively low, the border of clinical descisions in relation to the efficacy of the intervention will be at a lower value (closer to the zero-effect) than the MCID (Hultcrantz, 2017).

Drawing conclusions

For each relevant outcome measure, the scientific evidence was summarized in one or more conclusions based on literature where the level of evidence was determined according to the GRADE methodology. The working group weighed the beneficial and harmful effects of the intervention (overall conclusion). The overall evidential value was determined by the lowest evidential value found at one of the critical outcome measures. In complex decision-making processes in which many considerations also play a role in addition to the conclusions from the systematic literature analysis, an overall conclusion was omitted. In that case, the positive and negative effects of the interventions, together with all considerations, were weighed under the heading Considerations.

Considerations (from evidence to recommendation)

In order to propose a recommendation, in addition to (the quality of) the scientific evidence, other aspects were important as well and were taken into account, such as the expertise of the working group members, patient preferences, costs, availability of facilities and organisation of healthcare. These aspects were discussed in the paragraph Considerations.

Formulating recommendations

The recommendations answer the clinical question and are based on the available scientific evidence and the most important considerations, and a weighing of the beneficial and harmful effects of the relevant interventions. The strength of the scientific evidence and the weight given to the considerations by the working group together determine the strength of

the recommendation. In accordance with the GRADE methodology, a low probative value of conclusions in systematic literature analysis does not exclude a strong recommendation a priori, and weak recommendations are also possible with a high probative value. The strength of the recommendation is always determined by weighing all relevant arguments together.

Knowledge gaps

During the development of the guideline, a systematic literature search was performed. The results of which helped to answer the clinical questions. For each clinical question the working group determined if additional scientific research on this subject was desirable. An overview of recommendations for further research is available in the annex Knowledge Gaps.

Comment- and authorization phase

A draft version of the guideline has been commented on by the involved (scientific) associations, agencies and (patient) organizations. The comments were collected and discussed with the working group. The feedback was used to improve the guideline. Afterwards the working group made the guideline definitive. The final version of the guideline was shared with the involved scientific societies and was authorized by them. The full table with all commentaries (*in Dutch*) can be requested from the Knowledge Institute via secretariaat@kennisinstituut.nl.

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## Module 2: MRI in patients with cerebral aneurysm clip

### Clinical question

What is the policy of the MR safety expert for an MRI examination in a patient with a cerebral aneurysm clip?

*The clinical question includes the following sub-questions.*

1. What is the policy if the type of the implanted clip is known?
2. What to do if the type of clip cannot be traced?

### Introduction

Cerebral aneurysm clips are small, metallic clips used to treat an intracranial aneurysm or arteriovenous malformation. Although in the Netherlands nowadays only MR-conditional or MR-safe clips are applied, ferromagnetic type clips have been used until late in the last century. As this treatment is given to patients in different age groups including young adults, patients with an aneurysm clip, implanted in a period when ferromagnetic types were still in use, may still require an MRI for decades to come

If the type of cerebral aneurysm clip is known, it is possible to determine whether the patient can safely undergo an MRI examination, and if so under which conditions. However, in the past, patients have received clips that are an absolute contraindication for MRI, so caution is advised when the type of clip is unknown or it is not possible to determine with certainty what type of clip was implanted. In daily routine in the Netherlands, it is often unknown which the type of clip was implanted, as it is also in other countries (Mammourian, 2007; Kanal, 2013). However, on the basis of data that can often still be obtained, such as hospital and year of implantation, the risk can be estimated. The creation of an unambiguous National guideline would meet the need of MR safety experts in assessing this risk and create local guidelines.

### Search and select

The answer to clinical question 1 is clear, as it is well known which type of clips are or are not ferromagnetic. In the considerations that follow this has been further elaborated, yet, question 1 was not the clinical question addressed for the literature search.

In order to be able to answer the clinicial question 2, a literature analysis has been carried out aimed at the following search questions:

- What is the chance of negative outcomes (interaction clip versus MRI or effects on the patient) in patients with cerebral aneurysm clips undergoing an MRI examination? In the analysis of the search result, a distinction is made between clip type, clip material, type of MRI examination, scanner and field strength.
- In which period were cerebral aneurysm clips with an absolute contraindication for MRI implanted in the Dutch patient population?

<u>Search and select (Method)</u>

On 22 November 2016, the databases Pubmed and ScienceDirect were searched with relevant rather generic search criteria. The search accountability is displayed under the tab Search Accountability. Studies were selected on the basis of the following selection criterion: “relevant to the search queries”.

Based on title and abstract, 63 studies were pre-selected in the first instance. After consulting the full text, 44 studies were then excluded (see exclusion table under the Accountability tab), and 19 studies were finally selected. In examining these studies, two additional studies were identified in the reference lists describing a case of a patient with a

ferromagnetic aneurysm clip who had undergone an MRI study without complications, and one with a fatal outcome. These studies were therefore included, bringing the total to 21 studies included. On the basis of these studies, the following summary of the literature has been drawn up. Where relevant, these studies have also been used as a basis for the considerations.

In view of the type of literature found, the working group considered that a systematic literature analysis according to the GRADE-system (Guyatta, 2011) has no added value.

**Summary literature**

Description studies

Of the 21 publications evaluated, the majority (13) concerned experimental studies in which magnetic properties of clips were described, whether or not in a quantitative manner, or in which was looked at heating of clips as a result of exposure to radio frequency (RF) electromagnetic fields, or in which artifacts as a result of the presence of clips are described. In addition, two case studies have been described of MRI scans in patients with ferromagnetic aneurysm clips: a study of the incidence of implants that are an absolute contraindication for MRI, and a retrospective patient study in which MRI artifacts due to the presence of clips were studied. Finally, four letters were found with a warning for ferromagnetic clips, a strong criticism on an article describing magnetic properties of aneurysm clips, a plead for the importance of determining exactly which aneurysm clip one is dealing with for an MRI exam, and a call to set a date after which one can safely assume that only non-ferromagnetic clips have been implanted.

Results

*Question 1*: What is the chance of negative outcomes (interaction clip versus MRI or effects on the patient) in patients with cerebral aneurysm clips undergoing an MRI examination?

Two articles have been identified in the literature describing an MRI study of a patient with an in situ ferromagnetic aneurysm clip. In one case (Vari-angle clip, made of martensitic stainless steel 17-7 PH), that examination on an 1.5 T MRI scanner led to the death of the patient, probably due to a rupture in the arterial wall caused by attraction by the magnet and/or the torque exerted on the clip (Klucznik, 1993). This case led to an FDA warning about the danger of ferromagnetic aneurysm clips in the MRI environment (Johnson, 1993). In the other case (Heifetz clip, made of martensitic stainless steel 17-7 PH), it is described that the patient passed the examination without complications (Becker, 1988), although at a field strength of less than 1.5 T: at a lower field there is a lower attraction and torque than at 1.5 T.

Based on these two observations, little can be concluded about the probability of a fatal outcome of the MRI examination due to the presence of an aneurysm clip. However, these observations do show that having a ferromagnetic aneurysm clip does not necessarily mean that undergoing an MRI examination will be fatal. However, the individual risk for a patient with a ferromagnetic clip is extremely difficult to estimate (New, 1983), partly because it depends on a number of unknown factors such as the geometry of the clip, the orientation of the clip in the magnetic field and patient-specific properties such as the condition of the vascular wall.

From the fact that only one case study of a fatal incident with a ferromagnetic aneurysm clip was found, it cannot be concluded that safety risks are limited. A much more plausible

explanation for this low number is the worldwide existence of programs to screen patients for contraindications for MRI (Mamourian, 2012).

In addition to clips made of ferromagnetic stainless steel types including 17-7PH, 405SS, 404SS, 301SS, 304SS (all with Fe amount > 50%), there are also non-ferromagnetic clips made of alloys such as MP35N (mainly molybdenum, cobalt, chromium, nickel and ≤ 1% Fe), Elgiloy or the comparable Phynox (mainly molybdenum, cobalt, chromium, nickel and 10 to 15% Fe), or titanium or titanium alloys. A publication (McFadden, 1999) explicitly states that alloys with less than 50% Fe cannot become ferromagnetic in any way. This seems to be confirmed in articles in which no interaction of clips with the magnetic field is found (Shellock, 1998a), even after prolonged exposure of clips to the magnetic field (Kanal, 1999). However, to conclude that clips made of the above mentioned materials are not susceptible to motion or torque following exposure to the magnetic field of an MRI-scanner seems premature.

The literature also mentions the attraction and rotation of clips made of Phynox, Elgiloy or Titanium (Kanal, 1996; Sommer, 2004; Kakizawa, 2010). In this context, authors report concern due to ‘variablity in the degree of ferromagnetism' for clips of the same manufacturer and material (Kanal, 1996), and variations in alignment with the magnetic field for clips of different materials (Kakizawa, 2010). Based on their findings, Sommer at al. (2004) recommend 'MR imaging at 3.0 Tesla may be performed safely’ for these clips', although all the clips examined met the ASTM requirements, the titanium alloy clips are preferable in the 3-T environment for safety’s sake‘ (Kakizawa, 2010) and 'the variability in ferromagnetic response found is potentially problematic and patients with a clip should not be admitted to MRI unless the clip has been tested for ferromagnetic behavior prior to implantation, on site' (Shellock, 1998a).

In an article it was noted that there are no case reports showing incidents with patients with non-ferromagnetic clips (Shellock, 1998a, 1998b). The literature search carried out here also did not identify such case reports.

In the selected literature, no evidence has been found that aneurysm clips, made of any material, heat up significantly as a result of exposure to RF during MRI scans at 1.5 T and 3 T (Lauer, 2005; Ooka, 1996; Watanabe, 2007).

In the selected literature, no evidence has been found that oscillating gradients in MRI can cause a significant vibration of aneurysm clips.

*Question 2*: In which period were cerebral aneurysm clips with an absolute contraindication for MRI implanted in the Dutch patient population?

In the selected literature, no information is available to answer this question.

Some relevant numbers have been found in (Dewey, 2007). This German study showed that in the period November 1997 to December 2005, 0.41% of the referred outpatients, out of a group of 51,547 consecutive patients, had an absolute contraindication (not only clips) for MRI. More specifically, 13 ferromagnetic aneurysm clips were found in the database, i.e. in 0.03% of patients.

In general terms, the following can be noted. Clips produced until the "mid-80s" are particularly suspicious since until then MRI compatibility was not a design criterion (Johnson,

1993). It is important to note that in the past suppliers changed the material composition of clips in such a way that later specimens were of non-ferromagnetic material, but earlier specimens were of ferromagnetic stainless steel (Kanal, 1996). In May 1994, the FDA sent a letter to all clip makers demanding all information about their clips and testing status and, if this information was not available, asking to clearly label the product as untested for compatibility with MR scanners (Kanal, 1996). Shellock stated in 1998 that clips manufactered at that time almost without exception no longer posed any risk to the patient when exposed to the MRI environment (Shellock, 1998a, 1998b). It should be noted that MRI scanners with a field strength of 3 Tesla were still the exception at the time of publication.

Evidential power of the literature

There is no method available to determine the evidential value of the experimental studies reviewed. No patient systematic studies are available that have investigated the behavior of aneurysm clips in the MRI environment and their effects on the patient. The evidential value of conclusions drawn from the literature review is therefore limited.

**Conclusions**

*Search question 1: Chance of negative outcome for ferromagnetic clips.*

| | |
|---|---|
| **-**<br>**GRADE** | There is a chance that a patient with a ferromagnetic aneurysm clip can undergo the MRI examination without complications, but there is also a realistic chance that the examination turns out to be fatal. Estimating the individual risk to the patient is complicated and depends on the condition of the vessel wall on which the aneurysm clip is placed.<br><br>*Sources (Klucznik, 1993; Becker, 1988; Johnson, 1993; New, 1983)* |

| | |
|---|---|
| **-**<br>**GRADE** | Non-ferromagnetic clips appear to be safe in the MRI environment in terms of negative outcomes due to attraction or torque.<br><br>No significant heating of aneurysm clips is expected due to RF exposure during the MRI examination.<br><br>*Sources (Shellock, 1998a; Lauer, 2005; Ooka, 1996; Watanabe, 2007)* |

*Search question 2: Period of implantation of contraindicated clips in the Netherlands*

| | |
|---|---|
| **-**<br>**GRADE** | Based upon studies mainly from the United States, we inferred that the chance that a cerebral clip is ferromagnetic is high for implantation before the mid-80s and low after the mid-90s. It should be noted that the implantation of ferromagnetic clips continued for some time after the production of these clips ended.<br><br>*Sources (Johnson, 1993; Kanal, 1996; Shellock, 1998b)* |

**Considerations**

Summary of MR safety information from aneurysm clip manufacturers

An extensive database with MR safety information from aneurysm clips can be found on Shellock's website www.mrisafety.com. This website contains 349 types of clips in June 2018 (although subtypes are often bundled, e.g. the same model in different lengths). Of these, 173 are classified as 'MR safe', 157 as 'MR conditional' and 18 as 'MR unsafe'. The definition of MR safe used by Shellock differs from the definition of the ASTM standard and used by

suppliers. Shellock defines clips as MR safe, but also gives a field strength limit. This effectively changes the 'MR safe' definition to 'MR conditional' as their use in the MRI scanner is subject to limitations.

The 'MR conditional' clips have been divided into three subcategories by Shellock: the majority (146 clips) as 'conditional 6', six clips as 'conditional 5' and four clips as 'conditional 8'.

Condition 6 and 8 correspond to specific conditions as determined by the ASTM (condition 6: ≤ 3 T, whole body SAR ≤ 2 W/Kg and spatial gradient ≤ 7.2 T/m; condition 8: only two field strengths 1.5 T and 3 T, otherwise identical conditions). The category 'Conditional 5' refers to the conditions as published in the documentation of the manufacturers, and is MR conditional up to and including 3 T. Field strength restrictions are often the result of testing at only one field strength, and do not necessarily represent a real hazard at higher or different field strengths than those specified by the manufacturer.

Table 1 gives an overview of the aneurysm clips reported as MR unsafe. Table 2 gives an overview based on the material of the clip. The classification of the clips by manufacturer name is shown in Table 3. The years in which the particular type of clips were produced has not been published. The Shellock database is the basis for these tables, but data has been supplemented with information from the database of MagResource (MR:comp GmbH, Gelsenkirchen, Germany) and information from clip manufacturers.

**Table 1: List of MR unsafe clips based on risk of ferromagnetic forces***

| | |
|---|---|
| Codman Vari-Angle (17-7PH) | Kapp, Curved (404 SS), aneurysm clip |
| Codman Vari-Angle Micro (17-7PH) | Kapp, Straight (404 SS), aneurysm clip |
| Codman Vari-Angle Spring Micro (17-7PH) | Mayfield (301 SS), aneurysm clip |
| Drake (301 SS), aneurysm clip | Mayfield (304 SS), aneurysm clip |
| Drake (DR 14, DR 16, DR 21), aneurysm clip | McFadden (301 SS), aneurysm clip |
| Downs Multi-Positional, aneurysm clip | Scoville EN-57-J, EN-58-J** |
| Housepian, aneurysm clip | Sundt-Kees Multi-Angle (17-7PH) |
| Heifetz (17-7PH) | Pivot (17-7PH) |
| Cap (405 SS), aneurysm clip | Yasargil aneurysm clip (all FD models) 316 SS*** |

* List compiled from MRI.safety.com, MagResource and scientific literature.

** The material of the Scoville-Lewis clip was replaced from austenitic to martensitic SS during the production period (Dujovny, 2010). Because of this there is confusion about the MR safety of this clip since austenitic SS is assessed as MR safe (Shellock on MRISafety.com, where EN58-J is listed as MR safe at 1.5 T) and martensitic SS, described as 'EN57 J stainless steel', as MR unsafe (Scholler, 2005; Becker, 1988). However, Burtscher (1998) refers to En58J as ferromagnetic. Since it is unclear in the literature this clip should be considered MR unsafe.

*** The list contains a second entry for Yasargil: FD model, but this is a duplicate entry because it already falls under "All FD models". These clips have been classified as MR unsafe by Shellock, presumably after a letter from the manufacturer stating that the FD models are the only ones made of stainless steel (316 SS), and therefore not suitable for MRI. Nevertheless, Shellock classifies the Yasargil (316 SS) aneurysm clip as MR safe at 1.5 Tesla. Furthermore, Shellock reports that all other products (other than clips) made of stainless steel 316 SS MR are either MR safe or MR conditional. Becker (1988) also states that stainless steel 316 SS (or the Yasargil clip) is only slightly ferromagnetic, and therefore relatively safe.

**Table 2: Clip layout based on material used**

| Material | Remarks | Classification |
|---|---|---|
| 17-7PH | SS* | Always MR unsafe |
| 301SS, 304SS, 404SS, 405SS | | Always MR unsafe |
| DR14, DR16, DR21 | | Always MR unsafe |
| EN-57-J | British equivalent of 431SS martensite produced by Scoville | Always MR unsafe** |
| EN-58-J | British equivalent of austenitic 316SS produced by Scoville** | Although austenitic SS is not ferromagnetic (MR safe), the production of this clip may also release limited ferromagnetic material.<br>MR safe at 1.5 T |
| 316SS | E.g. Yasargil 316SS, weak ferromagnetic according to Becker, 1988. | MR safe at 1.5 T |
| Elgiloy | Cobalt alloy | MR safe at 1.5 T and at 3 T |
| MP35N | Cobalt alloy | MR safe at 1.5 T and 3 T, conditionally 6 at 3 T |
| PEEK | Only with Peter Lazic, aneurysm clip made entirely of fiber reinforced plastic | MR conditional 8 |
| Phynox | Cobalt alloy | MR safe at 1.5 T and 3 T, conditionally 5 at 3 T (e.g. different FE models from Yasargil) or conditionally 6 at 3 T |
| Perneczky SS | | MR safe at 1.5 T and 3 T |
| Titanium | | MR safe at 1.5 T and 3 T, conditional 5 at 3 T (e.g. different FT models from Yasargil), conditional 6 at 3 T or conditional 8 at 3 T. |
| Titanium alloy | Sometimes described as Ti6Al4V | MR safe at 1.5 and 3 T |
| Silver alloy | E.g. Stevens | MR safe at 1.5 T |

*SS , stainless steel is stainless steel.
** See note** table 1.

Further information on the materials used and the composition of the alloys can be found in the literature (Becker, 1988; Kossowsky, 1983).

**Table 3: clip format by manufacturer**

| Manufacturer | Remarks | Classification |
|---|---|---|
| Codman | MP35N | Conditional 6; 17-7PH 'vari-angle' models: MR unsafe |
| Downs | One type: 17-7PH | MR unsafe |
| Drake | 301SS,DR14,DR16,DR21 | All MR unsafe |
| Heifetz | 17-7PH | MR unsafe; Elgiloy: MR safe at 1.5 T |
| Housepian | One type | MR unsafe |
| Kapp | 404SS, 405 SS | Both MR unsafe |
| Kopitnik | Aesculap | MR conditional 5 by 1.5 T |
| Mayfield | 301SS, 304SS | Both MR unsafe |
| Mc Fadden | | 301SS:MR unsafe; MP35N:MR safe at 1.5 T |
| Olivercrona | One type | MR safe at 1.44T |
| Perneczky | | Titanium alloy: MR safe at 1.5 T; SS alloy (older models): MR safe at 3 T |
| Peter Lazic | Titanium and PEEK | All MR safe or MR conditional |
| Pivot | 17-7PH | MR unsafe |
| Spetzler | | Ti6Al4V (Titanium alloy): MR safe at 1.5 T and 3 T; pure titanium: MR safe at 3 T |
| Scoville | EN-58-Y/EN-57-Y | Depends on composition; if unknown: MR unsafe* |
| Stevens | Silver alloy | MR safe at 1.5 T |
| Sugita** | | Titanium alloy: MR safe at 1.5 T; Elgiloy, either MR safe at 1.5 T or safe at 3 T |
| Sundt-Kees | | MP35N: Conditional 6; 17-7PH: MR unsafe; P35N: MR safe at 1.5 T |
| Sundt Slim line Codman | MP35N | MR safe at 1.5 T and 3 T |
| Yasargil | | Phynox, Titanium: both Conditional 6, or Conditional 5 at 3 T, or safe at 3 T; Titanium alloy: MR safe at 1.5 T and 3 T; one austenitic SS clip, the FD series, is MR unsafe*** |

* See note** table 1.
** All Sugita products are according to the manufacturer MR Conditional (Titanium) or MR safe (Elgiloy) from the beginning of production.
*** See note*** table 1.

Summary of the information from implant incident databases.

For this module the following incident databases of implants have been searched:

- the recall database of the FDA;
- the database of the Health and Youth Care Inspectorate of the Netherlands (IGJ) with safety notifications as of December 15, 2015;
- the archive of the Health Care Inspectorate of the Netherlands (IGZ);
- the 'Implant' en 'Event' database of the International Consortium of Investigative Journalists (ICIJ).

The search accountability in these databases can be found in the table 'Search Databases of Recalls and Events'. In none of these databases have any reports been found that are relevant for this guideline module.

Survey on the use of type of aneurysm clips in the Netherlands

Because no information was found in the literature about question 2, the working group conducted a survey among all hospitals in the Netherlands where cerebral aneurysm clips

are placed amongthe heads of neurosurgical departments. This survey was completed in the spring of 2018, with a response rate of 100%. Tables 4 and 5 show the results of this survey.

**Table 4: Year of implantation from which it is unlikely a clip is ferromagnetic, differentiated between hospital of implantation, based on a survey among all hospitals in the Netherlands where cerebral aneurysm clips have been placed.**

| Hospital of Implantation | Year of implantation from which it is unlikely a clip is ferromagnetic |
|---|---|
| Amsterdam UMC, location AMC | 1995 |
| Amsterdam UMC, location VUMC | 1995 |
| Erasmus MC | 1995* |
| ETZ Elisabeth | 1990 |
| Haaglanden Medical Center | 1995 |
| ISALA | 1990 |
| LUMC | 1980 |
| MUMC | 2000 |
| Radboud UMC incl. Canisius Hospital | 1988 |
| UMCG | 1990 |
| UMCU | 1986 |

***** In the period 1989 to 1995, mainly Yasargil "FD" clips were implanted in Erasmus MC; these are classified as MR safe at 1.5 Tesla. These were still occasionally placed after 1995.

**Table 5: Expectation that a clip is or is not ferromagnetic when the hospital of implantation is unknown in the Netherlands (determined on the basis of Table 4 and estimated number of implantations per institute).**

| Date of implantation in the Netherlands | Certainty that clip is not ferromagnetic* | Chance that clip is ferromagnetic |
|---|---|---|
| 2000 and later | >99.9% | <0.1% |
| 1995 - 1999 | 97% | unknown** |
| 1990 - 1994 | 81% | unknown** |
| 1986 - 1989 | 47% | unknown** |
| 1980 - 1985 | 3% | unknown** |
| before 1980 | 0% | >90% |

* When asked in the survey, each institute responded unequivocally to the question as to the date from which all implanted clips were non-ferromagnetic. In order create this table, it was assumed that before the year in question "100% non-ferromagnetic" only ferromagnetic clips had been implanted per institute, whereas in the years prior to this, some of the clips used were already non-ferromagnetic. The percentage of non-ferromagnetic clips can therefore be higher.

** The use of ferromagnetic clips in the 1980s to 2000s could not be determined unequivocally**.**

It should be noted that in the years prior to the policy that all implanted clips were not ferromagnetic, a significant proportion of the clips were also non-ferromagnetic. However, we could not unequivocally determine the percentage of these. The working group assumes that in countries/hospitals with a comparable standard of health care, a similar policy has been pursued with regard to type of clip implantations.

Classification of implant risks in main classes

In general, risks from metallic implants in the MRI can be classified in the following main classes:

1. Risk of displacement and rotation of the implant due to the presence of the static magnetic field and the spatial gradient of this field.
2. Risk of implant heating due to interaction with the applied radio frequency (RF) field.
3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal.
4. Artifact in the MRI image.
5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner.
6. Risk of interference with implant function.

*1.Risks due to displacement and rotation*

The effect of displacement and rotation of the clip in the magnetic field and the spatial gradient is created respectively by the force that each magnetic material (diamagnetic, paramagnetic and ferromagnetic) experiences in a magnetic field gradient, and by the torque in a magnetic field. For ferromagnetic materials in nowadays clinically used MRI scanners (1.5 to 3 Tesla), these forces and torques are large relative to gravity. The forces for diamagnetic and paramagnetic materials with low magnetic susceptibility, on the other hand, are negligible in these MRI systems (McFadden, 1999). For paramagnetic materials with a high magnetic susceptibility, these forces can be important, since they depend on the magnetic field gradient, the magnetic susceptibility as well as on the shape of the object, and must be considered for each type of material.

Aneurysm clips are made of different metals and alloys (Mc Fadden, 2012). In the past, many clips were made of ferromagnetic material. Early clips were made of ferromagnetic stainless steel (such as SS 301-405, or DR). Later, materials for the production of clips were changed to non-ferromagnetic materials such as titanium, and titanium and cobalt alloys such as MP35N, Phynox, and Elgiloy.

The worst possible consequence of displacement and rotation of a ferromagnetic aneurysm clip is the death of the patient. Such a case was reported long ago and reported in the literature (Klucznik 1993), and recently a second patient with a clip, placed in 1982, died after MRI in the USA (communication MRI Safety Group ISMRM, Sept 2016). In contrast, a case of a ferromagnetic clip in a low-field MRI (<0.6T) was described in which there were no consequences for the patient (Becker, 1988). The exact risk is difficult to estimate, and depends on multiple factors. For this reason, ferromagnetic aneurysm clips remain an absolute contraindication for undergoing an MRI study (Klucznik, 1993; Johnson, 1993; Shellock, www.mrisafety.com). Aneurysm clips made of non-ferromagnetic material (such as Phynox, Elgiloy, MP35N, titanium or titanium-based alloys, and austenitic stainless steel species) are MR conditional. In May 1994, the FDA wrote to all clip manufacturers requesting all data and information regarding the tests performed and, if no tests had been performed, to state in the user information that ‘you have not tested your device for compatibility with MR imaging devices’ (Kanal, 1996).

Because of the risk and the obligation of MR safety labeling, all manufacturers have, as far as known, abandoned ferromagnetic materials. As a result, only clips placed longer ago (summarized in Table 1) are of ferromagnetic material. In 1998, a Shellock study revealed that ferromagnetic clips were no longer supplied by the manufacturers (Shellock, 1998a, 1998b; McFadden, 1999). It is highly unlikely that manufacturers will bring new aneurysm

clips onto the market that are ferromagnetic, as MRI diagnostics play a role for neurosurgeons to follow-up this patient group.

*MRI status classification*

Before 1994, there was no consensus on quantifying ferromagnetic properties of implants (Kanal, 1996). Until then, studies describing ferromagnetic properties of implants should therefore be interpreted with caution. In 1994, the American Society for Testing and Materials (ASTM, 1994) published a standard requiring that the so-called deflection angle should be measured to evaluate the magnetic properties of aneurysm clips. When this angle is less than 45 degrees, gravity exerts a greater force on the clip than the magnetic field of the MRI scanner. The ASTM thus recommends only a test for displacement, but not a test for torque (Kangarlu, 2000). This test was described later (ASTM, 2011). If the clip type is available separately, it is possible to perform this test yourself based on the ASTM F2503 guideline (ASTM, 2015).

There is no publication in the literature to substantiate that no MR unsafe clips were made after a certain date. However, Shellock states in 1998 that since that period no clips have been produced that pose a risk to patients in the MRI environment (Shellock, 1998a). However, this does not mean that previously produced (possibly unsafe) clips could not have been implanted at a later date.

The MRI safety of clips is determined by the manufacturer and tested at one or more field strengths. Although the MR conditional indication as determined at a certain magnetic field strength or with a certain scanner type does not automatically apply to other field strengths or scanners, Shellock has shown that the current clips for which an MR conditional classification applies at 1.5 Tesla do not show excessive torque or displacement in a 3 Tesla scanner (Shellock, 2010).

*2. Risk of implant heating due to RF field interaction*

From a physics point of view, the risk of heating tissue around a cerebral aneurysm clip can be expected to be negligible due to the short (non-resonant) length of the clips. The wavelength of RF waves at the resonant frequency in water in clinical scanners is significantly greater (Shellock, 2010). Watanabe et al. measured a temperature difference of less than 1°C in clips made of titanium and Elgiloy at 3 T in the most unfavorable position; at the side of the bore (Watanabe, 2007). The data from this study should be interpreted with some care, since Watanabe refers to wavelengths of meters in air at 3 T, while the effective wavelength *in vivo* is lower, of the order of 17 to 90 cm at 3 T depending on the type of tissue.

Typical heating as reported by the manufacturer Aesculap in a Yagarsil clip is 1.8°C in titanium and 2.5°C in Phynox clips at 3 T after 15 minutes of scanning. Manufacturers classify 154 of 349 type clips as MR conditional, with a maximum whole body SAR of 2 W/kg.

However, the manufacturers report the maximum temperature increase as measured in the gel phantom setup, not the additional temperature increase due to the clip alone. Given the test conditions where the gel heats up already without the implant, this kind of reporting overestimates the actual temperature increase due to the clip. In addition, *in vivo* additional cooling occurs due to the blood flow in the vessel from which the aneurysm is clipped.

The working group is of the opinion that the actual heating as a result of a cerebral aneurysm clip is below 1°C in MR systems of 3 T and below and that therefore no additional conditions are required at SAR level.

*3. Risk of vibration or induction of currents by the oscillating magnetic field gradient*
The risk of vibration or induction of currents from the aneurysm clip by the oscillating magnetic field gradient - applied for spatial coding - can be expected to be negligible due to the small surface area of interaction with the gradient fields. In addition, no indications for this have been found in the literature.

*4. Artifact in the MRI image*
Due to a local magnetic field disturbance, the presence of an aneurysm clip will lead to image artifacts. The size and shape of these artifacts partly depends on the size, shape, type of material and spatial orientation of the clip, but also on the field strength of the MRI scanner and the type of MRI sequence.

Several publications report on artifacts around aneurysm clips. Brothers concluded that in patients using Sugita-clips (made of cobalt-chromium alloy) and Drake-tourniquets, the diagnostic information obtained with MRI appears to be more valuable than that obtained with CT in the same patients (Brothers, 1990). Artifacts around titanium clips (0.4 to 1.2 $cm^2$) appear to be about one third the size caused by 'conventional clips' made of cobalt-chromium alloy (1.0 to 3.6 $cm^2$) (Lawton, 1996). A study comparing a titanium clip with clips made of Phynox, Elgiloy, MP35N, NiCoCrMo and CrNiMo showed artifacts around the titanium clip that were 2.5 to 5 times smaller than those around the other materials (0.7 $cm^2$ and 1.8 to 3.9 $cm^2$ respectively, Shellock, 1998b). A case study of a patient who underwent an MRI scan with a ferromagnetic aneurysm clip showed that this clip produces such image artifacts that the images of a large part of the brain are virtually worthless for diagnosis (Becker, 1988).

Metal artifacts are unavoidable, but a number of measures can be taken to reduce the adverse impact of metal artifacts: choosing lower field strength (1.5 T instead of 3 T), applying spin echo instead of gradient echo technique, shortening echo time, applying techniques for reduction of metal artifacts, swapping frequency and phase coding direction or opting for a smaller voxel size or higher readout bandwidth.

When the area of interest is close to the clip, or when the artifact is expected to be large, consideration should be given to whether imaging using MRI has sufficient diagnostic value.

*5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner.*
Due to the size of the implant, the forces due to the Lenz effect on the clip are negligible at 1.5 T and 3 T.

*6.Risk of interference with implant function.*
The only risk on interaction of the functioning of the clip is by displacement or rotation, a risk that has already been addressed.

<u>*Considerations for unknown clip type*</u>
When the exact type of aneurysm clip cannot be determined, it can be taken into account that the chance of finding someone in the general population with a ferromagnetic clip is limited. A large retrospective study showed that 0.03% of the referred outpatients wore a

ferromagnetic clip (Dewey, 2007). This is not equal to the probability that an unknown clip is ferromagnetic.
In the case of an unknown type of aneurysm clip, a conservative policy can be pursued and, as a precaution, it can be decided not to perform an MRI scan (Mamourian, 2007). However, it should be taken into account that withholding diagnostics by means of MRI can have negative consequences for the patient, and therefore both aspects should be weighed against each other (Kanal, 2013).

Based on the literature and previous considerations, the risk of complications when using MRI in the presence of intracranial clips has been estimated as shown in Table 6, depending on the year and hospital of implantation of the clip.

Figure 1 shows a flowchart with a decision tree for MRI studies in patients with a cerebral aneurysm clip.

**Table 6: Expectation that an unknown type of cerebral aneurysm clip is not safe for MRI; as estimated by the working group. For quantitative translation see Table 2 of the general introduction.**

| Hospital of implantation | Year of implantation | Probability of damage from unsafe aneurysm clip in MRI* |
|---|---|---|
| Netherlands** | 2000 and later | Unlikely |
| | 1990 - 1999 | Unusual to rare*** |
| | 1989 and earlier | To be expected |
| Elsewhere | 1995 and later | Unusual |
| | 1994 and earlier | To be expected |

* This only applies to horizontal closed bore whole body MRI systems of 1.5 T and 3 T.
** The Netherlands or in a country/hospital with an equivalent level of health care.
*** This is based on the fact that before all the clips were non-ferromagnetic, most of the clips produced since the nineties were not ferromagnetic, and that a ferromagnetic clip will not always cause damage.

**Recommendations**

Determine the year and hospital of implantation of the cerebral aneurysm clip in a patient with an MRI indication. This can be done on the basis of the patient's traceable data, such as the operation report, EPD, or by asking the patient or his/her physician.

If the year of implantation is 2000 or later and the clip is placed in the Netherlands*, MRI can be performed and the clip is 'MRI allowed for 1.5 and 3 T'.
If implantation in the Netherlands took place before 2000, determine on the basis of Table 4 whether the clip is unlikely to be ferromagnetic. If so, the clip is 'MRI allowed for 1.5 and 3 T'.

In all other cases, determine the type of clip and check Table 1 to see if the clip MR is unsafe or not. If the clip MR is unsafe, no MRI should be performed. If the clip type is not in Table 4, the clip is 'MRI allowed for 1.5 and 3 T'.
The type of clip can be traced by the operation report, EPD or by asking the physician who placed the clip.

* The Netherlands or in a country/hospital with an equivalent level of health care

*If the above information cannot be retrieved*:
Investigate whether the patient has previously undergone MRI after clip implantation.
If case of previous MRI:

- Have the MR safety expert assess the images, looking at the applied field strength and, if possible, type of MR scanner. Based on artifact size and applied MR sequence, an estimate can be obtained on the degree of ferromagnetism of the clip.

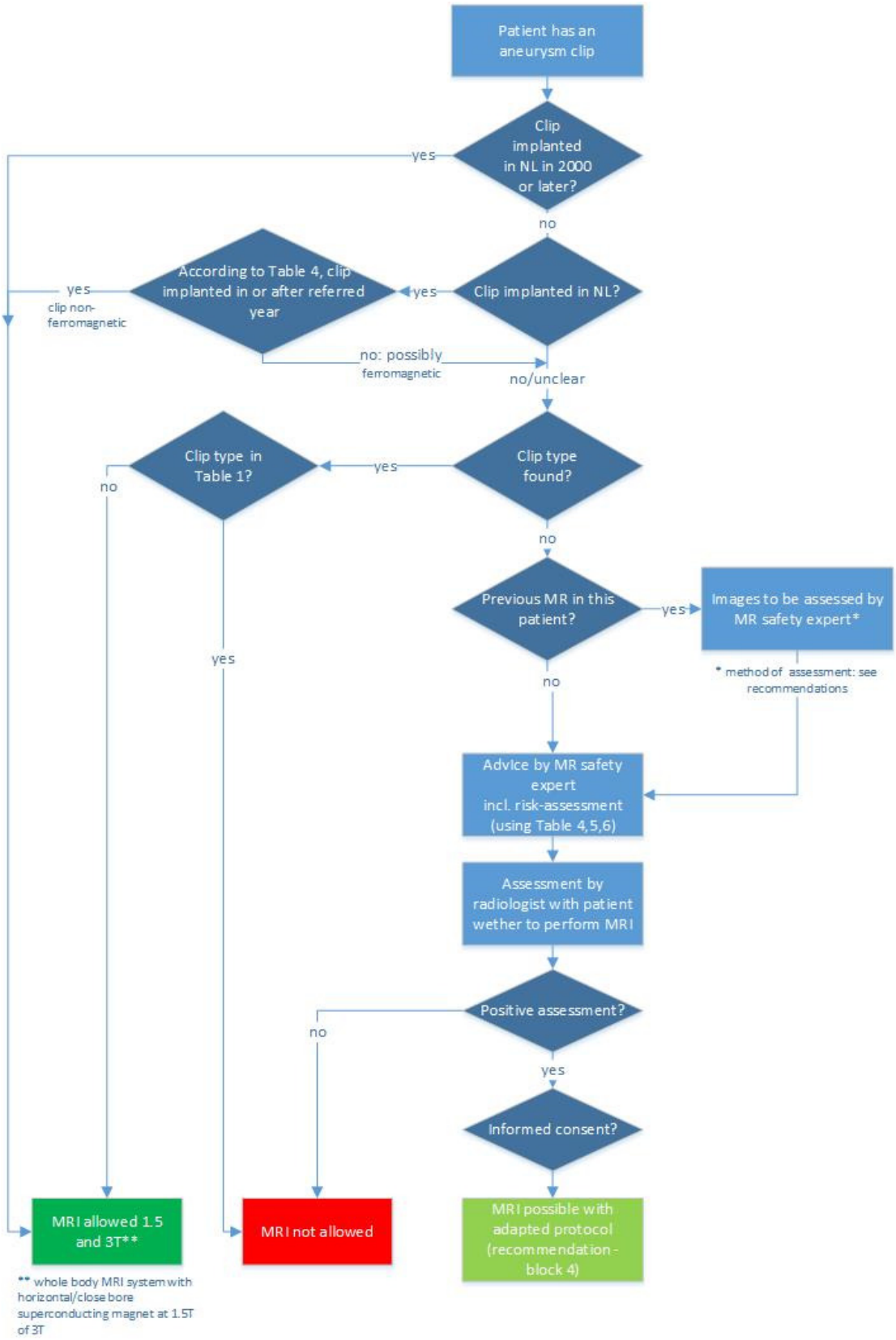
- Artifacts must also be assessed in relation to the requested MRI examination. When artifacts lead to a non-diagnostic scan, the MRI examination should not take place.
- A new MRI examination is allowed up to a maximum of the previous strength with a horizontal closed bore whole body MRI: this is to be assessed by the MR safety expert.

When the type of clip cannot be determined, estimate, based on the hospital and the year of clip implantation with Table 4, 5 and or 6, the probability of injury to the patient by MRI, and, in consultation with the radiologist and patient, make a trade-off between the probability of injury and the importance of diagnosis.

Scan, if it is unclear whether the clip MR is safe but an MRI examination is necessary according to the following recommendations:

- Inform the patient and ask his/her consent;
- Scan at 1.5 T if the probability of a ferromagnetic clip is greater than ‘rare’;
- As far as possible, keep the patient's head centered in the opening of the scanner, and not at the edges of the bore opening. This is because in the center of the MRI bore the forces are smaller than at the edge of the bore opening. Preference for patient positioning 'feet first';
- Support/fix the patient's head as best as possible to prevent movement;
- Do not scan on an open-bore MRI system.

**Figure 1: Flowchart with decision tree for MRI examination in patient with a cerebral aneurysm clip**

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# Annex to module 2

## Validity and Maintenance

| Module [1] | Coordination [2] | Year of Authorization | Next assessment validty module [3] | Frequency of review on validaty [4] | Who supervises validity [5] | Relevant factors for changes in recommendation [6] |
|---|---|---|---|---|---|---|
| cerebral aneurysm clip | NVKF | 2019 | 2024 | Every five years | NVKF | New literature |

[1] Module name

[2] Coordinator of the module (this can differ per module and can also be shared)

[3] Maximum after five years

[4] (Semi-)yearly, once in two years, once in five years

[5] Directing association, shared directing associations, or (multidisciplinary) working group that is maintained

[6] Ongoing research, changes in compensation/organization, availability of new resources

## Implementation plan

| Recommendation | Timeline for implementation: <1 year, 1 to 3 years or >3 years | Expected effect on costs | Preconditions for implementation (within specified timeframe) | Possible barriers to implementation [1] | Actions to be taken for implementation [2] | Responsible for actions [3] | Other remarks |
|---|---|---|---|---|---|---|---|
| 1-4 | <1 year | Cost reduction | MRI Availability | None | Spreading the guideline | NVKF, hospitals and locally involved care providers | None |

[1] Barriers can be at the level of the professional, at the level of the organization (the hospital) or at the level of the system (outside the hospital). Think for example of disagreement in the country regarding the recommendation, insufficient motivation or knowledge of the specialist, insufficient facilities or personnel, necessary concentration of care, costs, poor cooperation between disciplines, necessary reallocation of tasks, etcetera.

[2] Think of actions that are necessary for implementation, but also actions that are possible to promote implementation. Think for example of checking recommendation during quality visit, publication of the guideline, development of implementation tools, informing hospital administrators, arranging good compensation for a certain type of treatment, making collaboration agreements.

[3] Those responsible for implementing the recommendations will also depend on the level of barriers. Barriers at the professional level will often have to be solved by the professional association. Barriers at the organizational level will often be the responsibility of the hospital administrators. In solving barriers at the level of the system, other parties, such as the NZA and health insurers, are also important.

**Search Accountability**

A 'structured review' of the scientific literature was carried out using the digital databases in Pubmed and Sciencedirect, from which 63 articles were selected for further study on relevance to this guideline by working group members after pre-selection. These were then reviewed by 2 persons.

| Database | Search criteria | Total |
|---|---|---|
| Pubmed | Magnetic resonance imaging or MRI<br>Publication date > 1970/01/01<br>Safety<br>Aneurysm<br>Clip or clips | 63 |
| Pubmed | Magnetic resonance imaging or MRI<br>Publication date > 1970/01/01<br>Aneurysm<br>Clip or clips | |
| ScienceDirect | Magnetic resonance imaging or MRI<br>Publication date > 1999/01/01<br>Safety<br>Aneurysm<br>Clip or clips<br>And not surgery | |

Of these 63 articles, 19 are relevant to the search queries, and are included in the summary.

Search Databases of Recalls and Events

| Database | Search criteria[1] | Total |
|---|---|---|
| FDA Recalls database[2]<br><br>searched on 25-1-2019 | 1 'MR' OR 'magnetic' (329)<br>2 concerns implant and MRI (9)<br>3 concerns relevant implant for this module (0)<br><br>= 0 | 0 |
| IGJ database safety notifications[3]<br>*notifications from 15-12-2015*<br><br>searched on 29-1-2019 | 1a 'MR' (22)<br>1b 'MRI' (15)<br>1c 'magnetic' (11)<br>2 concerns implant and MRI (4)<br>3 concerns relevant implant for this module (0)<br><br>= 0 | |
| IGZ archive[4]<br><br><br>searched on 17 and 29-1-2019 | 1a 'MR' (98)<br>1b 'MRI' (92)<br>1c 'magnetic' (27)<br>2 concerns implant and MRI (0)<br>3 concerns relevant implant for this module (0)<br><br>= 0 | |
| ICIJ database Implants[5]<br><br><br>searched on 18-1-2019 | 1a 'MR' (38)<br>1b 'MRI' (17)<br>2 concerns implant and MRI (0)<br>3 concerns relevant implant for this module (0)<br><br>= 0 | |
| ICIJ database Events[5]<br><br>searched on 25-1-2019 | 1a Data_notes contains "aneurysm" OR "clips") AND Reason contains "mr" OR "magnetic" (0)<br><br>= 0 | |
| ICIJ database Events[5]<br><br>searched on 18 and 25-1-2019 | 1a 'MR' (603)<br>1b 'magnetic' (185)<br>2 Assess whether the hits are not from the FDA database (0) | |

| | | |
|---|---|---|
| | = 0<br>*This database has an overlap with the FDA database2.* | |

1 The databases have limited and different possibilities to search them. The search strategies chosen is via 'MRI'. Subsequently, all hits were read and assessed whether they concern an implant, and then whether the implant is relevant for this module. In addition, the databases have limitations, an example of this is an MRI related report of an implant from the IGZ database which isn't found in the FDA database because there the link to MRI had dissapeared.

2 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

3 https://www.igj.nl/onderwerpen/waarschuwingen-medische-hulpmiddelen/documenten.

4 https://igj.archiefweb.eu/?subsite=igz#archive.

5 https://medicaldevices.icij.org

## Exclusion Table

**after reading the full article**

| Author and year | Reasons of exclusion |
|---|---|
| Chandela 2011 | This article is not about MRI safety for clips. |
| Chen 2011 | This article is not about MRI safety for clips. |
| Dujovny 1996 | Results of specific tests of clips, which does not provide additional information for search queries. |
| Dujovny 1997 | Comment on another article (Kanal 1996). Does not contain information about clips. |
| Ferris 2007 | This study inventoried the way in which screening for a number of MRI contraindications takes place in Australia. Contains no information relevant to the search queries. |
| Fleckenstein 1997 | Comment on another article (Kanal 1996). Does not contain information about clips. |
| Friedrich 2016 | Study on the reduction of MRI artefacts (through MRI sequence choices), which only mentions that patients were included with MR safe clips. Therefore not relevant for the search queries. |
| Gold 1989 | This paper is about surgical clips other than aneurysm clips. |
| Gonner 2002 | This paper covers the size of image artifacts of clips that are MR safe. Therefore not relevant for the search queries. |
| Tomb 2005 | This paper deals with image artifacts of all kinds of implants including clips. Not relevant for the search queries. |
| Grieve 1999 | This paper deals with image artifacts of clips that are MR safe. Therefore not relevant for the search queries. |
| Henrichs 2011 | This paper discusses precautions for intra-operative MRI scans during resection of brain tumors. |
| Ho 1999 | In this paper one characterizes a paramagnetic alloy (Elgiloy). Not relevant for the search queries. |
| Joint 2008 | General description on how to create a safe environment around the MRI scanner, without specific search queries. |
| Kato 1996 | Results of specific tests of clips, not performed according to ASTM-standard and without relevant, additional insights regarding the search queries. |
| Kean 1985 | This paper reports a brief test in which it was determined that eight types of aneurysm clips are ferro-magnetic. This information is not new and does not offer any new insights in the search queries. |
| Krayenbuhl 2011 | In this study, somatosensory evoked potential (SEP) is compared to post-operative ischemia using DWI MRI measurements. No relevant information for the search queries. |
| Laakman 1985 | This paper deals with image artifacts of all kinds of implants at 0.3 T avoiding aneurysm clips. Therefore not relevant for the search queries. |
| Lawton 1996 | In this study, mechanical properties, biocompatibility and MRI artifacts of titanium aneurysm clips were investigated, from which it was concluded that patients with a titanium clip can safely enter an MRI scanner. The study does not provide any insights with regard to the search queries. |
| Marinho 2014 | This article is not about MRI. |
| Macfarlane 2008 | This study only describes a local initiative to create a database with information on MRI compatibility of implants. |
| Nagatani 1998 | This article deals with the mechanical properties of titanium clips and image artifacts. No relevant information for search queries. |
| Ont Health Technol Assess Ser 2006 | This study focuses on the safety of an embolisation procedure and does not provide any clues regarding the search queries. |
| Beepgrass 1995 | This paper provides a description of the first clinical experiences with the use of titanium clips and does not provide any clues regarding the search queries. |

| | |
|---|---|
| Pirasteh 2016 | This study describes a method of online screening of patients for contraindications for MRI, but does not provide information on safety and aneurysm clips. |
| Pride 2000 | This paper concludes, based on a follow-up of 46 patients, that MRI can be performed safely in patients with non-ferromagnetic aneurysm clips. Therefore, no insights with regard to the search questions. |
| Romner 1989 | Study at 0.3 T concluding that non-ferromagnetic aneurysm clips are safe at the field strength tested and further that ferromagnetic clips result in unusable MRI images, without further consideration to the safety of scanning those clips. Therefore, no insights with regard to the search queries. |
| Shellock 1993 | This paper provides no information relevant to the search queries other than that it states that caution should be exercised when the type of implant is not known. |
| Shellock 1988 | This paper gives an overview of tested implants of which the results will be processed on MRIsafety.com in view of the author, in such a way that there are no new insights regarding the search queries. |
| Shellock 1988 | This paper (also from 1988) gives an overview of 36 tested implants of which the results will be processed on MRIsafety.com in view of the author, in such a way that there are no new insights regarding the search queries. |
| Shellock 1991 | Comprehensive review paper on implant safety when conducting MRI examinations without new information relevant to the search queries. It is recommended not to expose ferromagnetic aneurysm clips to the static magnetic field of the MRI scanner. |
| Shellock 1998 | In this study, 22 aneurysm clips were tested in the vicinity of a 0.2T extremity MRI scanner, such that the clips are exposed to very different fields than relevant for the search queries. |
| Shellock 1998 | This paper deals with image artifacts at 1.5 T due to clips, but does not cover security issues. Therefore not relevant for the search queries. |
| Shellock 2002 | This paper also gives an overview of in this case 109 tested implants at 3 T of which the results, given the author, will be processed on MRIsafety.com, in such a way that there are no new insights regarding the search queries. |
| Shellock 2002 | In this study, a type of MRI scanner was used other than the 1.5 T and 3 T whole body systems for which this guideline is being drawn up. |
| Scaffolding 1999 | This study is about the effectiveness of a clip to treat an aneurysm. It has been found that an MRI angiography scan due to image artifacts cannot be used to assess whether the surgery was successful. Therefore, no additional information is relevant for the search queries. |
| Sutherland 2008 | This paper describes the development of a new type of clip made of non-ferromagnetic material. The manuscript does not provide any new information regarding the search queries. |
| Syms 2000 | This study is about a different type of implant than aneurysm clips. |
| Teitelbaum 1990 | This study is about a different type of implant than aneurysm clips at different field strengths than what this guideline focuses on. |
| Van Loon 1997 | This paper describes a comparison between CT versus MRI angiography to determine the success of aneurysm clip placement, not looking at the safety of the MRI study itself. |
| Weber 1991 | This letter-to-the-editor does not provide any new insights relevant to the search queries. |
| Wichmann 1997 | This article focuses on artifacts in imaging as a result of the clips and as such does not provide insights into the search queries. |
| Yang 2008 | This paper describes a surgical study, without findings relevant in the context of MRI safety. |